# EXHIBIT E

Page 341

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC,
REPAIR SYSTEM PRODUCTS,
LIABILITY LITIGATION

MDL NO. 2:12-MD-02327

MDL NO. 2327

DOSEPH R. GOODWIN
THIS DOCUMENT RELATES TO US DISTRICT JUDGE
CAROLYN LEWIS, ET AL. V. DETHICON, INC.
CASE NO. 2:12-CV-04301

FRIDAY, NOVEMBER 15, 2013

- - -

Deposition of Prof. Dr. Med.

Uwe Klinge, Volume II, held at the Quellenhoff
Hotel, Monheimsallee 52, 52062 Aachen, Germany,
commencing at 8:35 a.m., on the above date,
before Carrie A. Campbell, Registered
Professional Reporter, Certified Realtime
Reporter, Certified Shorthand Reporter,

GOLKOW TECHNOLOGIES, INC. 877.370.3377 ph|917.591.5672 fax deps@golkow.com

and Certified Court Reporter.

Golkow Technologies, Inc. - 1.877.370.DEPS

Page 342	Page 344
1 INDEX	1 APPEARANCES:
2 PAGE 3 APPEARANCES	2 3 ANDERSON LAW OFFICES, LLC BY: BENJAMIN HOUSTON ANDERSON, ESQUIRE 4 ben@andersonlawoffices.net 1360 West 9th Street, Suite 215 5 Cleveland, Ohio 44113 (216) 592-8384
9 10 EXHIBITS No. Description Page 11 12 Interdisciplinary S2e Guideline for the Diagnosis and Treatment of Stress 12 Urinary Incontinence in Women 13 AWMF online 346 13 14 "EAU Guidelines on the Surgical 349	6 AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC 7 BY: DANIEL J. THORNBURGH, ESQUIRE dthornburgh@awkolaw.com 8 17 East Main Street, Suite 200 Pensacola, Florida 32502 9 (850) 202-1010
Treatment of Stress Urinary  14 Incontinence."  15 Guidelines on Urinary Incontinence 350  15 16 American Urological Association 353 positions statements	Counsel for Plaintiffs  10  11 THOMAS COMBS & SPANN, PLLC BY: DAVID B. THOMAS, ESQUIRE  12 dthomas@tcspllc.com
16 17 "Position Statement on Restriction of Surgical Options for Pelvic Floor 17 Disorders" 18 "ICS Fact Sheets, A Background to 355 18 Urinary and Fecal Incontinence"	PHILIP J. COMBS, ESQUIRE  13 pcombs@tcspllc.com 300 Summers Street, Suite 1380  14 Charleston, West Virginia 25301 (304) 414-1807
19 "Urinary Incontinence, the Management 359 of Urinary Incontinence in Women" 20 "The New Objective Measurements to 378 20 Characterize the Porosity of Textile Implants" 21 21 "Tensile Properties of Five Commonly 386	16 ALSO PRESENT: Julie Filarski, Anderson Law Offices, LLC  17  18
Used Midurethral Slings Relative to the TVT"  Hernia Repair Sequela"  496	19 20 21
23 23 "Comparison of Long-Term 501 Biocompatibility of PVDF and PP 24 Meshes"	22   23   24
Page 343	Page 345
1 24 Pathology report for Carolyn Lewis 565 25 Findings from Klinge review of the 615 2 slides 26 "Impact of Polymer Pore Size on the 624 3 Interface Scar Formation in a Rat Model"	1 2 (Klinge Exhibit 12 marked for 3 identification.)
4 27 "The Argument for Light-Weight 633 Polypropylene Mesh in Hernia Repair"	5 MR. THOMAS: Before the
5 28 Ethicon documents, 641 ETH.MESH.01782867 6 29 E-mail from Joerg Holste to Jonathan 644	6 deposition, I told Mr. Anderson during 7 the inquiry yesterday about the 8 redacted exhibit concerning the
Meek dated April 22, 2009, FTH.MESH.02148431 - ETH.MESH.02148432 Clinical expert report from Piet 645	9 meeting in Suvretta in 2003. I've
8 Hinoul, ETH.MESH.08315779 - ETH.MESH.08315810 9 31 "Demand the most proven technology 647 when selecting a midurethral sling.	been advised that the company has already produced an unredacted copy of that document in another production.
10 Make data and safety your choice" 32 PowerPoint slides 653 11 33 Letter from Christoph Walther to 654 Quentin,	13 I've asked for it and hope to have it 14 when they wake up. So I'll produce it
12       HMESH_ETH_00379723         13       (Exhibits attached to the deposition.)         14       CERTIFICATE668         ACKNOWLEDGMENT OF DEPONENT	to you as soon as I have it.  MR. ANDERSON: Thank you for doing that.
15 ERRATA	18 DIRECT EXAMINATION (Witness previously sworn) 19 QUESTIONS BY MR. THOMAS: 20 Q. Doctor, when we closed
18 19 20 21 22	yesterday, we were talking about who a doctor could consult with to understand the risks
22 23	23 related to the using of mesh for the

2 (Pages 342 to 345)

1 Do you recall that? 2 A. Yes. 3 Q. And I believe you identified 4 for me an organization in Germany that you  1 guidelines that you discuss 2 online on the computer? 3 A. Please, I had to lead to lead 1 on the computer? 4 Q. I am sorry.	sed vesterday
2 A. Yes. 2 online on the computer? 3 Q. And I believe you identified 3 A. Please, I had to lead	
3 Q. And I believe you identified 3 A. Please, I had to le	
	ook, sorry.
	3311, 33113.
5 called the AWMF; is that correct? 5 When you referred	d to the AWMF
6 A. Yes. 6 guidelines	
7 Q. Let me show you what I've 7 A. Yeah.	
8 marked as Exhibit Number 12. As I understand 8 Q did you go to t	the computer
9 it from those people who looked for me, 9 to consult the computer to	
10 Exhibit Number 12 is an English version and 10 guidelines?	Tille those
the short version of the AWMF registry for 11 A. When I hadn't local terms of the AWMF registry for 12 I A. When I hadn't local terms of the AWMF registry for 13 I A. When I hadn't local terms of the AWMF registry for 14 I A. When I hadn't local terms of the AWMF registry for 15 I A. When I hadn't local terms of the AWMF registry for	oked to this
12 the diagnosis and treatment of stress urinary 12 yes.	oked to tins,
13 incontinence in women. 13 Q. Do you have a harmonic of sucess utilities of sucess u	ard copy of the
14 Is that fair? 14 guidelines from the compu	~ *
15 MR. ANDERSON: Objection. 15 A. No.	uter:
16 QUESTIONS BY MR. THOMAS: 16 Q. All right. Do you	u know whother
17 Q. Are you familiar with this 17 Exhibit 13 are the guideling	
18 document, Doctor? 18 at online?	les that you looked
19 A. With this English, no, I never 19 A. I tried to figure of	out the data
20 read it. 20 of when these guidelines h	
,	
Page 347	Page 349
1 marked as Exhibit Number 13. It's the long 1 been changed in the document	
2 version, and it's in German. 2 made my research. It's sor	
3 Do you recognize that document? 3 text. If you like, I can try	
4 MR. ANDERSON: Well, objection. 4 here, but it's the recommen	ndation of surgical
5 This is a 62-page document and if you 5 therapy.	
6 want to ask him if he has if by the 6 Q. Okay. I don't wa	
7 cover of this or he can read 62 pages. 7 A. So I'm not sure w	whether this is
8 MR. THOMAS: All I want to 8 the last version here.	
9 know, Ben, is whether this is the 9 Q. That's fine.	I
organization that he discussed 10 (Klinge Exhibit 14	4 marked for
yesterday consulting online for the 11 identification.)	
12 guidelines for the treatment of stress   12 QUESTIONS BY MR. TH	HOMAS:
urinary incontinence. I don't want 13 Q. Let me hand you	what's been
him to read the whole document. We 14 marked now as Deposition	
don't have time to do that. 15 Deposition Exhibit Number	er 14, Dr. Klinge, is
16 MR. ANDERSON: Different 16 a document titled "EAU G	duidelines on the
17 question. 17 Surgical Treatment of Stre	ess Urinary
18 Is this AWMF the organization 18 Incontinence."	
19 that you mentioned yesterday as far as 19 Simple question, h	nave you seen
20 you can tell? 20 this document before?	
THE WITNESS: Yes. I mentioned 21 A. No, I've not seen	it.
22 this. 22 Q. And the date on i	
23 QUESTIONS BY MR. THOMAS: 23 the 7th, 2012, when it was	
Q. And did you consult the 24 published online on Septer	

3 (Pages 346 to 349)

1	Page 350		Page 352
1	is that correct? On the left right in the	1	Urological Association to be authoritative in
2	middle?	2	the field of treatment of stress urinary
3	A. Yeah. That's correct.	3	incontinence?
4	Q. Are you familiar with the	4	A. I cannot comment on this. I
5	European Association of Urology?	5	know from my colleagues here that there are
6	A. No.	6	various societies taking care of the problem
7	(Klinge Exhibit 15 marked for	7	of incontinence and they're competing.
8	identification.)	8	They're sometimes with conflicting with
9	QUESTIONS BY MR. THOMAS:	9	different assumptions, different advices or
10	Q. Let me show you what's been	10	less.
11	marked as Deposition Exhibit Number 15.	11	To my knowledge from all of the
12	Exhibit Number 15 is a document	12	discussions with them, there is not one
13	titled Guidelines on Urinary Incontinence,	13	single society that is authoritative, yeah,
14	Text Update, March 2013. It reads, "This	14	that is able to give recommendations for the
15	pocket version aims to synthesize the	15	woman either treated by urologist or
16	important clinical messages described in the	16	gynecologist. But, of course, you find a lot
17	full text and is presented as a series of	17	of these different societies. Maybe this is
18	evidence summaries and graded action-based	18	an expression that there are different
19	recommendations which follow the standard for	19	opinions as well.
20	levels of evidence used by the EAU."	20	Q. And you said, "I know from my
21	Have you seen Exhibit Number 15	21	colleagues here." Is that conversations that
22	before today?	22	you've had with colleagues at the hospital
23	A. No, I haven't seen it.	23	where you work?
24	Q. Doctor, are you familiar with	24	A. Yes. We have a close
	Page 351		Page 353
1	an organization known as the American	1	collaboration with Professor
2	Urological Association?	2	Kirschner-Hermanns, for example, she has been
3	A. Familiar, if you mean that I	3	the leader of the incontinence center.
4	have ever heard of it or noticed it, I think	4	Q. And that's the incontinence
5	so, yes.	5	center at the hospital that's part of the
6	Q. Do you consider the American	6	university?
7	Urological Association to be authoritative in	7	A. Yeah.
8	the field of stress urinary incontinence	8	(Klinge Exhibit 16 marked for
9	treatment?	9	identification.)
10	MR. ANDERSON: Objection.	10	QUESTIONS BY MR. THOMAS:
11	Dr. Klinge is not a urologist and he's	11	Q. Let me show you what's been
1	not here being offered as a urologist	12	marked as Deposition Exhibit Number 16. This
12		13	is titled "Position Statements of the
13	nor the treatment options of SUI, and		
13 14	as I stated yesterday, and so all of	14	American Urological Association." It's dated
13 14 15	as I stated yesterday, and so all of these questions about treatment	14 15	American Urological Association." It's dated at the bottom November 2011.
13 14 15 16	as I stated yesterday, and so all of these questions about treatment recommendations for a urologist or a	14 15 16	American Urological Association." It's dated at the bottom November 2011.  Is it fair to understand that
13 14 15 16 17	as I stated yesterday, and so all of these questions about treatment recommendations for a urologist or a urogynecologist clearly are outside of	14 15 16 17	American Urological Association." It's dated at the bottom November 2011.  Is it fair to understand that you've not seen this position statement of
13 14 15 16 17 18	as I stated yesterday, and so all of these questions about treatment recommendations for a urologist or a urogynecologist clearly are outside of the scope of his expert report and the	14 15 16 17 18	American Urological Association." It's dated at the bottom November 2011.  Is it fair to understand that you've not seen this position statement of the American Urological Association?
13 14 15 16 17 18 19	as I stated yesterday, and so all of these questions about treatment recommendations for a urologist or a urogynecologist clearly are outside of the scope of his expert report and the reasons that he's being offered as an	14 15 16 17 18 19	American Urological Association." It's dated at the bottom November 2011.  Is it fair to understand that you've not seen this position statement of the American Urological Association?  MR. ANDERSON: Same objections
13 14 15 16 17 18 19 20	as I stated yesterday, and so all of these questions about treatment recommendations for a urologist or a urogynecologist clearly are outside of the scope of his expert report and the reasons that he's being offered as an expert. If counsel wants to continue	14 15 16 17 18 19 20	American Urological Association." It's dated at the bottom November 2011.  Is it fair to understand that you've not seen this position statement of the American Urological Association?  MR. ANDERSON: Same objections I stated before.
13 14 15 16 17 18 19 20 21	as I stated yesterday, and so all of these questions about treatment recommendations for a urologist or a urogynecologist clearly are outside of the scope of his expert report and the reasons that he's being offered as an expert. If counsel wants to continue to ask questions about it, but I'm	14 15 16 17 18 19 20 21	American Urological Association." It's dated at the bottom November 2011.  Is it fair to understand that you've not seen this position statement of the American Urological Association?  MR. ANDERSON: Same objections I stated before.  THE WITNESS: I don't recall
13 14 15 16 17 18 19 20 21 22	as I stated yesterday, and so all of these questions about treatment recommendations for a urologist or a urogynecologist clearly are outside of the scope of his expert report and the reasons that he's being offered as an expert. If counsel wants to continue to ask questions about it, but I'm going to move to strike all of it.	14 15 16 17 18 19 20 21 22	American Urological Association." It's dated at the bottom November 2011.  Is it fair to understand that you've not seen this position statement of the American Urological Association?  MR. ANDERSON: Same objections I stated before.  THE WITNESS: I don't recall whether this is exactly. I recall
13 14 15 16 17 18 19 20 21	as I stated yesterday, and so all of these questions about treatment recommendations for a urologist or a urogynecologist clearly are outside of the scope of his expert report and the reasons that he's being offered as an expert. If counsel wants to continue to ask questions about it, but I'm	14 15 16 17 18 19 20 21	American Urological Association." It's dated at the bottom November 2011.  Is it fair to understand that you've not seen this position statement of the American Urological Association?  MR. ANDERSON: Same objections I stated before.  THE WITNESS: I don't recall

4 (Pages 350 to 353)

	Page 354		Page 356
1	but it's not my focus to list all of	1	QUESTIONS BY MR. THOMAS:
2	these various societies and various	2	Q. Doctor, are you familiar with
3	aspects.	3	the International Incontinence Society?
4	(Klinge Exhibit 17 marked for	4	A. Yes. I know them.
5	identification.)	5	Q. Let me hand you what's been
6	QUESTIONS BY MR. THOMAS:	6	marked as Deposition Exhibit Number 18.
7	Q. Let me show you what I've	7	Deposition Exhibit Number 18 is titled "ICS
8	marked now Deposition Exhibit Number 17.	8	Fact Sheets, A Background to Urinary and
9	Deposition Exhibit Number 17 is	9	Fecal Incontinence," prepared by the
10	from the American Urogynecologic Society, and	10	publications and communications committee,
11	it's titled "Position Statement on	11	July 2013.
12	Restriction of Surgical Options for Pelvic	12	Have you seen this document
13	Floor Disorders."	13	before?
14	Have you seen Exhibit 17	14	A. Not as a printout version, but
15	before?	15	I repeatedly am going to the website because
16	A. Maybe. I'm not sure.	16	they offered a lot of interesting tools for
17	Q. Did you consider the position	17	making research and how to investigate all
18	of the American Urogynecologic Society in the	18	these. So it's an interesting website from
19	formation of your opinions in this case?	19	the society.
20	MR. ANDERSON: Objection. Same	20	Q. Do you
21	objection before.	21	A. And among this, there is I
22	THE WITNESS: Please, can you	22	made a lot of downloads from the society.
23	say it again?	23	Q. Why did you do that?
24	out it again.	24	A. Because I'm interested. I want
	Page 355		Page 357
1	QUESTIONS BY MR. THOMAS:	1	to be informed of what happens. There's so
2	Q. Did you consider the position	2	many contradicting information and to get an
3	of the American Urogynecologic Society in the	3	overview, yeah, I'm a scientist and,
4	formation of your opinions in this case?	4	therefore, it is my duty to go into the
5	MR. ANDERSON: Objection. The	5	problems.
6	question is not fair.	6	Q. Let's go
7	Do you want him to read the	7	A. To try to learn of it.
8	entire document because how could he	8	Q. Let's go to page 13 of
9	know whether he considered the	9	Exhibit 18, please.
10	position if he doesn't know what it	10	On the left side, the second
11	is. My objection stands. He's not	11	full half reads, "Definitive therapy for SUI
12	going to be asked any of these	12	is surgical and involves restoring urethral
13	questions and you know that and it's	13	support through use of a sling. Worldwide
14	not anywhere in his report nor is it	14	mid-urethral slings comprised of synthetic
15	in his reliance materials, but if you	15	mesh have become the treatment of choice for
16	want to keep asking, please, feel free	16	SUI. Long-term data are robust and
17	to.	17	demonstrate durable efficacy and a very low
18	MR. THOMAS: Thank you, I will.	18	complication rate particularly in experienced
19	I have a limited amount of time here.	19	hands."
20	MR. ANDERSON: You do.	20	Do you agree with that
21	MR. THOMAS: You can have a	21	statement of the ICS?
22	standing objection to that.	22	MR. ANDERSON: Same objections.
23	(Klinge Exhibit 18 marked for	23	THE WITNESS: The I don't
1	identification.)	24	think that I'm in the moment that

5 (Pages 354 to 357)

	Page 358		Page 360
1	I'm able to give an opinion in what	1	Q. Why did you go to the NICE
2	woman, at what stage of the disease,	2	website?
3	what therapy may be the best.	3	A. Same answer as some minutes
4	When they said here they are a	4	before; to get informed the search and
5	low complication rate, we talked about	5	literature is one of our most important tools
6	what does it mean low, can we be sure	6	and there has been in February last
7	that it is low, that is a question we	7	year the question whether we have access to
8	can have intense discussions about it.	8	all of these things and I would like to point
9	My topic or my so far as I	9	out that at the university we have an almost
10	understood, my question was whether	10	unlimited access to all things that are
11	the use of the Prolene®, when it is	11	published there to correct this impression
12	coming to complications, whether this	12	that it is restricted to the journals I get
13	is a problem of the material. Whether	13	personally.
14	there are some basic requirements that	14	Q. I didn't suggest that.
15	makes it imperative to use the most	15	A. No, it was from the last year
16	heaviest weight mesh from a hernia	16	or in February there has been the discussion,
17	surgery for the use of this. That was	17	there has been the question whether do our
18	the question that I wanted to address	18	getting these specific journal and I just
19	by looking all these things.	19	wanted to take this opportunity to clarify
20	So even if there is only one	20	that we have huge possibilities to access.
21	patient with a complication that is	21	Q. I understand that.
22	not necessary because of using the	22	The computer is a wonderful
23	wrong requirements, that was the	23	thing, isn't it?
24	question that I wanted to address.	24	A. It has changed completely our
	Page 359		Page 361
1	But I'm not able to say their	1	work.
2	requirements for the societies or so.	2	Q. Doctor, let's go back to your
3	And I have no doubt that there are	3	report, please, which is Exhibit Number 11.
4	some patients taking a big benefit by	4	On page 2 of Exhibit 11 under
5	the use of slings.	5	the summary of your opinions, you say, "The
6	(Klinge Exhibit 19 marked for	6	mesh excuse me, the Prolene® mesh in TVT®
7	identification.)	7	is a heavy-weight mesh
8	QUESTIONS BY MR. THOMAS:	8	MR. ANDERSON: Can you show us
9	Q. Let me hand you what I've	9	where you are?
10	marked now as Deposition Exhibit Number 19.	10	MR. THOMAS: Right at the top
11	Deposition Exhibit Number 19	11	of the page.
12	A. Yeah, that is the NICE, yeah,	12	MR. ANDERSON: Thank you.
13	the National Institute.	13	QUESTIONS BY MR. THOMAS:
14	Q. Is NICE it's called it's	14	Q. Doctor, in page 2 of
15	titled "Urinary Incontinence, the Management	15	Exhibit 11, you state in your report under
16 17	of Urinary Incontinence in Women," issued	16 17	the heading, "The Prolene® mesh in TVT® is a
18	September 2013. And it's issued by the	18	heavy-weight mesh ('over engineered').  In that paragraph, you say,
19	organization called NICE, the National Institute For Health and Care Excellence.	19	"Any pelvic mesh designed with this much
20	Is this the document to which	20	excess surface area and weight unreasonably
21	you referred yesterday in your testimony?	21	increases the risk of injury to the patient
22	A. I downloaded, if I remember	22	and is a less safe design."
23	correctly, about 10, 15 documents from the	23	Did I read that correctly?
22	• • • • • • • • • • • • • • • • • • • •		· · · · · · · · · · · · · · · · · · ·
24	website from NICE. So this is one of it.	24	A. Yes.

6 (Pages 358 to 361)

	Page 362		Page 364
1	Q. And my question is when you say	1	to 2 microns and create a
2	that this mesh design unreasonably increases	2	multifilament made of polypropylene,
3	the risk of injury, compared to what?	3	then you are right, completely right.
4	A. To a material that is, in	4	That is but this has been a an
5	fact, the most important thing, you have to	5	important part of our discussions
6	do it in comparison. If you compare the	6	because we, that is coming from
7	108 grams of the Prolene® mesh with the	7	Aachen, that is has been our work
8	42 grams of Gynemesh® for the 34 grams of	8	to stick on the importance of the
9	ULTRAPRO <sup>TM</sup> , it has a surplus, it has more	9	pores and not of the weight.
10	material, it has more surface. So if you	10	So but sometimes it is more
11	compare these two, you have more contact area	11	easy to reduce it to this to make it
12	to the tissue and, therefore, you will have	12	better understandable for the people.
13	intensified tissue reaction.	13	Q. Doctor, do you have any
14	So if there is no need to have	14	clinical data to which you can point to
15	this amount of material, if you can reduce	15	support your opinion that the Prolene® mesh
16	it, if you can produce, if there are some	16	increases the risk of injury in the treatment
17	facts that allow you to reduce the amount of	17	of stress urinary incontinence above other
18	material of the Prolene® mesh by half, then	18	materials for the same application?
19	you will have an improved tissue reaction	19	MR. ANDERSON: Objection.
20	and, therefore, you will lessen the scar	20	THE WITNESS: As I pointed out
21	formation, you will lessen the risks for the	21	yesterday, the clinical data
22	patient. That is it. Prolene® mesh is at	22	unfortunately that are provided, they
23	the maximum. In comparison to all other	23	are too limited to allow this
24	meshes, it's the maximum of the weight of the	24	consequence; however, the basic
	Page 363		Page 365
1	material that is placed in this area and,	1	principle that heavy-weight, a huge
2	therefore, it is, of course, it is	2	amount of material locally, small pore
3	heavy-weight. I think it's the heaviest	3	size, that this is linked to an
4	monofilament mesh that I know, and if you can	4	increased risk, there are several
5	reduce the amount of material, that has been	5	studies showing it and not least
6	the sense of our work, then you improve the	6	because of this in the guidelines, in
7	tissue reaction and reduce the risk.	7	the meta-analysis for surgical meshes
8	Q. Didn't we decide yesterday that	8	for hernia repair they're usually
9	weight was not the determining factor in the	9	already is a statement that you have
10	intensity of the foreign body reaction?	10	to consider light-weight and large
11	MR. ANDERSON: Objection to	11	pore.
12	form.	12	QUESTIONS BY MR. THOMAS:
13	Go ahead.	13	Q. You referred to a meta-analysis
14	THE WITNESS: In fact, that	14	for surgical meshes for hernia repair.
15	is yeah. If you have a Prolene®	15	Have you considered the
16	with these fibers and just reduce the	16	meta-analysis for the use of meshes for
17	amount of material, using a similar	17	stress urinary incontinence?
18	fiber, the same fiber, but just reduce	18	A. We mentioned yesterday I'm
19	the amount of material, of course, you	19	deeply aware about the fact that the limited
20	will increase the pore sizes, you will	20	value of meta-analysis.
21	reduce the material and you will	21	Q. Okay.
22	improve the tissue reaction.	22	A. It just it is helpful to
		1 2 2	confirm the importance of weight and none
23 24	If you just stick to the weight and change the fiber from 120 microns	23 24	confirm the importance of weight and pore size. In general, that this is that has a

7 (Pages 362 to 365)

	Page 366		Page 368
1	strong impact of the clinical results. There	1	That there are some similarities when
2	is no doubt about it. But as I pointed out	2	you place meshes in living tissue,
3	yesterday, it is impossible to see or to	3	that you have some similarities.
4	prove any inferiority or superiority of any	4	There are depending on the specific
5	specific device.	5	location, there can be some
6	Q. Also in your answer, you	6	differences in the tissue reaction,
7	referenced several studies showing this basic	7	but there are very important aspects
8	principle.	8	that are quite similar that a mesh
9	Are these all animal studies?	9	behaves similarly in the various areas
10	A. No, there is if you are	10	from the point of the histological
11	if you're trying to figure out what is the	11	analysis.
12	relevance of this mesh material discussion in	12	There are considerable
13	the field of hernia surgery, and the field of	13	differences in the biomechanics and
14	hernia surgery is a little bit older than	14	there we know that pelvic floor has
15	this for the pelvic floor and a lot of and	15	different biomechanics. We have a
16	we introduced the meshes, I think, earlier,	16	similar area in the reenforcement of
17	if you try to figure out what is the	17	the diagram where we have some forces
18	relevance there, then you find there are	18	as well. So the biomechanical problem
19	several meta-analysis meanwhile summarizing	19	makes it as a functional difference to
20	clinical studies, and there are guidelines	20	the hernia mesh. That is even more in
21	for the clinical treatment based on these	21	another respect when you're taking a
22	clinical trials and giving the recommendation	22	hernia mesh to use it in another
23		23	functional condition. It's a concern
24	to use large pore material, reduce light-weight meshes in the treatment for	24	and problem.
21	Page 367	21	
			Page 369
1	the treatment of hernia patients.	1	QUESTIONS BY MR. THOMAS:
2	So that confirms that the	2	Q. Let me try my question again
3	principle to think or to consider the mesh	3	and maybe you didn't understand it.
4	material and the weight and the pore size,	4	What I'm trying to understand,
5	that is well-accepted in the hernia society,	5	we were talking about clinical studies used
6	yes.	6	to analyze the extent to which mesh causes
7	Q. Is it fair to understand,	7	problems in the pelvic floor strike that.
8	Doctor, that you're relying upon your	8	The goal of my question was to
9	training, education and experience in	9	try to determine whether there are clinical
10	connection with the care and treatment of	10	studies on which you rely to analyze the
11	hernias to support your position that mesh	11	problems of complications with the use of
12	used in the treatment of stress urinary	12	mesh for the treatment of stress urinary
13	incontinence has the same risks as the mesh	13	incontinence, and I think you told me that
14	that's used in hernia repair?	14	you rely on your clinical experience in
15	MR. ANDERSON: Objection.	15	hernia for that information.
16	Go ahead.	16	Is that true?
17	THE WITNESS: Of course, my	17	MR. ANDERSON: Objection to the
18	knowledge of the Prolene® is based on	18	form of the whole question.
19	our preclinical studies that we did in	19	Go ahead.
20	the animal models, from our clinical	20	THE WITNESS: No, that is, of
21	experience, from the experience we	21	course, not true because to my
22	have got from hernia patients.	22	opinions, it is it is necessary to
23	Overall, everything confirmed that the	23	see whether there are some
24	tissue response is quite similar.	24	complications when using it as a

8 (Pages 366 to 369)

1 A. I'm not able to give you a list 2 of all of the documents I've downloaded 3 during the past years. I regularly are 4 looking to the literature, and I know it's 5 hundreds of documents every week are coming, 6 some new. So, yeah, several. I looked at 7 several of them. 8 Q. Can you tell me one? 9 A. One of these publications? 10 Q. Yes, just one. 11 A. Sling. As I told you, it's the 12 NICE meta-analysis. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties. 19 It that suggest that the design of the Prolene® 2 mesh increases the risk of injury to a 3 patient over in the treatment of stress 4 urinary incontinence over a larger pore, 1 lighter-weight mesh; is that true? 6 MR. ANDERSON: Objection. 7 Asked and answered again. 8 THE WITNESS: It isn't true 9 because you didn't reduce it to the 10 pelvic floor. So if you made it in 11 general 12 QUESTIONS BY MR. THOMAS: 13 Q. Oh, I think I did. 14 A. You just asked me if I'm 15 told you, the AWMF, it is study for PVDF 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.		Page 370		Page 372
documents, there are some specific complications which are different from the two from hernia surgery. So you that there has been a comparison of different materials as it has been done in the hernia in the field of hernia surgery. So you that there has been a comparison of different materials as it has been done in the hernia in the field of hernia surgery where we make randomized controlled trials comparing light-weight and large pore meshes. I don't know whether I don't know in the moment a study where someone compared two different slings with the outcome. But as we discussed yesterday, clinical studies are very limited in clarifying whether one material really is better than the other. It is very likely that if you well. You have to include it into this.  Q. What literature have you the area of include it into this.  Q. What literature have you the arise from the use of mesh in the doring the past years. I regularly are looking to the literature, and I know it's hundreds of documents I've downloaded during the past years. I regularly are looking to the literature, and I know it's hundreds of documents every week are coming, some new. So, yeah, several. I looked at several of them.  A. I'm not able to give you a list of all of the documents I've downloaded during the past years. I regularly are looking to the literature, and I know it's shundreds of documents every week are coming, some new. So, yeah, several. I looked at several of them.  A. Can you tell me one?  A. One of these publications?  A. One of these publications?  Q. Yes, just one.  A. Sling, As I told you, it's the lot told you, the AWMF, it is study for PVDF meshes from Norway that has been published this year. There has been several studies in comparing the textile properties.	1	sling, and as you know from the	1	Asked and answered.
d those from hernia surgery. So you thave to look to the specific 5 have to look to the specific 5 different materials as it has been done in the hernia in the field of hernia surgery where we make randomized controlled trials comparing light-weight and large pore meshes. I don't know whether -1 don't know whether -1 don't know whether at don't know win the moment a study where someone compared two different slings with the outcome. But as we discussed yesterday, clinical studies are very limited in clarifying whether one material really is better than the other. It is very likely that if you make such a study that you get nonsignificant results due to the variation in your collectives.  Q. What literature have you at list of all of the documents I've downloaded during the past years. I regularly are a looking to the literature, and I know it's hundreds of documents every week are coming, some new. So, yeah, several. I looked at several of them.  Q. Can you tell me one?  A. I'm not able to give you a list of all of the documents I've downloaded during the past years. I regularly are a looking to the literature, and I know it's hun		- · · · · · · · · · · · · · · · · · · ·	2	
those from hernia surgery. So you have to look to the specific different materials as it has been done in the hernia - in the field of hor consequences.  However, the general opinion 8 whether it's heavy-weight, whether 9 whether it's heavy-weight, whether 9 light-weight and large pore meshes. I don't know whether I don't know in the moment a study where someone to gether.  QUESTIONS BY MR. THOMAS: 13 outcome. But as we discussed yesterday, clinical studies are very that you need to go to the specific 16 literature to learn what may be the 17 consequences of the use of mesh for the 17 consequences of the use of mesh for the 18 treatment of stress urinary incontinence? 18 make such a study that you get nonsignificant results due to the variation in your collectives.  Q What literature have you 22 considered to understand the complications 24 looking to the literature, and I know it's hundreds of documents I've downloaded 3 during the past years. I regularly are 4 looking to the literature, and I know it's 5 hundreds of documents every week are coming, some new. So, yeah, several. Hooked at several of them. 7 several of them. 7 several of them. 7 several of them. 7 A. Sling. As I told you, it's the 11 told you, the AWMF, it is study for PVDF meshes from Norway that has been published 17 this year. There has been several studies 17 this year. There has been several studies 18 comparing the textile properties. 18 different materials as it has been done in the hemia - in the field of hemia surgery where we make randomized controlled rish controlled in the hemia - in the field of hemias urgery where we make randomized controlled trandomized controlled trandomized controlled trandomized controlled trandomized controlled trandomized controlled trandomized controlled randomized controlled trandomized controlled trandomized controlled randomized				
5			l .	
6 literature what may be some 7 consequences. 8 However, the general opinion 9 whether it's heavy-weight, whether 10 it's a higher risk than another, you 11 have to take all of this information 12 together. 13 QUESTIONS BY MR. THOMAS: 14 Q. Okay. Is it your testimony 15 that you need to go to the specific 16 literature to learn what may be the 17 consequences of the use of mesh for the 18 treatment of stress urinary incontinence? 19 A. You have to include it into this. 20 Q. What literature have you 21 which arise from the use of mesh in the 22 treatment of stress urinary incontinence? 23 which arise from the use of mesh in the 24 treatment of stress urinary incontinence? 25 hundreds of documents every week are coming, 26 some new. So, yeah, several. I looked at 27 several of them. 28 Q. Can you tell me one? 29 A. One of these publications? 29 Q. Yes, just one. 20 Q. Okay. 21 NICE meta-analysis. 22 Q. Okay. 23 that there are no it's true that true? 24 to do not significant results it is that true? 25 lighter-weight and large pore meshes. I don't know whether I don				
7 hernia surgery where we make randomized controlled trials comparing whether it's heavy-weight, whether it's heavy-weight or I missed it. So a general, there are clinical studies and wiscome.  7 hernia surgery where we make randomized controlled trials comparing the tweight and make unadomized controlled trials comparing the tweight whether one it's heavy-weight or I make such a study where someone to don't know whether I don't know in the member and only know whether I don't know in the member and only know whether I don't know in the member and only know whether I don't know in the moment a study where someone to don't know whether I don't know in the moment a study where someone to don't know whether I don't know in the moment a study where someone to don't know whether I don't know in the moment a study where someone to don't know whether I don't know in the moment a study where someone to don't know whether I don't know in the moment a study where someone to don't know whether I don't know in the moment a study where someone to don't know whether I don't know in the moment a study where someone to don't know whether I don't know in the moment a study where someone to don't know thether I don't know in the moment a study where someone to don't know in the moment a study where someone to don't know in the moment a study where someone to don't know in the moment a study where someone to don't know in the moment a study where someone to don't know in the moment a study where someone to dout me satisfaction. I			l .	
B		· · · · · · · · · · · · · · · · · · ·	l .	
9   whether it's heavy-weight, whether   10   it's a higher risk than another, you   10   don't know whether I don't know in   11   thave to take all of this information   11   the moment a study where someone   12   together.   12   compared two different slings with the   12   outcome. But as we discussed   14   yesterday, clinical studies are very   15   that you need to go to the specific   15   limited in clarifying whether one   material really is better than the   16   other. It is very likely that if you   18   treatment of stress urinary incontinence?   18   make such a study that you get   nonsignificant results due to the   variation in your collectives.   20   variation in your collectives.   21   Q. What literature have you   21   QUESTIONS BY MR. THOMAS:   22   variation in your collectives.   23   variation in your considered to understand the complications   23   during the past years. I regularly are   4   looking to the literature, and I know it's   5   hundreds of documents every week are coming, some new. So, yeah, several. I looked at   5   several of them.   20   Can you tell me one?   8   Q. Can you tell me one?   9   A. One of these publications?   9   A. One of these publications?   9   A. One of these publications?   9   A. That their - it is - as I   told you, the AWMF, it is study for PVDF   meshes from Norway that has been published   16   that comparing the textile properties.   18   soon make such a study that you get   nonsignificant results due to the   variation in your clienties understance?   20   variation in your clienties due to the   variation in your clienties are very   variation in			l .	
10 it's a higher risk than another, you have to take all of this information to tegether.  12 cogether.  13 QUESTIONS BY MR. THOMAS: 14 Q. Okay. Is it your testimony that you need to go to the specific literature to learn what may be the consequences of the use of mesh for the well. You have to consider this as well. You have to include it into this.  20 Q. What literature have you which arise from the use of mesh in the reatment of stress urinary incontinence?  11 A. I'm not able to give you a list of all of the documents I've downloaded during the past years. I regularly are looking to the literature, and I know it's hundreds of documents every week are coming, some new. So, yeah, several. I looked at several of them.  12 Q. Can you tell me one?  23 A. One of these publications?  24 Q. Can you tell me one?  25 Q. Yes, just one. 26 Q. Yes, just one. 27 Q. Okay. 28 Q. Okay. 39 A. One of these publications? 40 Q. Okay. 41 C. Can you tell me one? 42 A. That their – it is – as I told you, the AWMF, it is study for PVDF meshes from Norway that has been published this year. There has been several studies.  18 C. Can you telt me one remained from Norway that has been published this year. There has been several studies.			l .	1 0
have to take all of this information together.  QUESTIONS BY MR. THOMAS: 13 outcome. But as we discussed QUESTIONS BY MR. THOMAS: 14 Q. Okay. Is it your testimony 15 that you need to go to the specific 16 literature to learn what may be the 17 consequences of the use of mesh for the 18 treatment of stress urinary incontinence? 19 A. You have to consider this as 20 well. You have to include it into this. 21 Q. What literature have you 22 considered to understand the complications 23 which arise from the use of mesh in the 24 treatment of stress urinary incontinence? 24 treatment of stress urinary incontinence? 25  Q. Is it true, simple question, 26 that there are no—it's true that there are 27  no clinical studies about which you're aware  Page 371  A. I'm not able to give you a list 29 of all of the documents I've downloaded 30 during the past years. I regularly are 41 looking to the literature, and I know it's 55 hundreds of documents every week are coming, 66 some new. So, yeah, several. I looked at 77 several of them. 8 Q. Can you tell me one? 9 A. One of these publications? 9 A. One of these publications? 10 Q. Yes, just one. 11 A. That their — it is — as I 12 told you, the AWMF, it is study for PVDF 13 meshes from Norway that has been published 14 A. That their — it is — as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 the moment a study where someone comparison to heavy-weight or I missed it. 18 outcome. But as we discussed 15 limited in clarifying whether one 16 material really is better than the 17 other. It is very likely that if you 18 make such a study that you get 19 other. It is outcome. But as we discussed 19 outcome. But as we discussed 16 material really is better than the 17 other. It is yery likely that if you 18 make such a study that if you 18 make such a study where someone 18 material really is better than the 17 other. It is every likely that if you 18 make such a study that every likely that if you 18 make such a study that evely likely th		• •		
12 together. 13 QUESTIONS BY MR. THOMAS: 14 Q. Okay. Is it your testimony 15 that you need to go to the specific 16 literature to learn what may be the 17 consequences of the use of mesh for the 18 treatment of stress urinary incontinence? 19 A. You have to consider this as 20 well. You have to include it into this. 21 Q. What literature have you 22 considered to understand the complications 23 which arise from the use of mesh in the 24 treatment of stress urinary incontinence? 25 during the past years. I regularly are 26 looking to the literature, and I know it's 27 several of them. 28 Q. Can you tell me one? 29 A. One of these publications? 29 Q. Yes, just one. 20 Q. Yes, just one. 30 Q. Yes, just one. 40 Q. Can you tell me one? 41 Q. Can you tell me one? 42 Can you tell me one? 43 Q. Can you tell me one? 44 Can you fell me one? 45 A. That their it is as I told you, the AWMF, it is study for PVDF meshes from Norway that has been published this year. There has been several studies 40 comparing the textile properties. 41 Comparing the textile properties. 42 comparied two different slings with the outcome. But as we discussed yeyesterly geter yetseld yeyesterly, clinical studies are very likely that if you mate it on then. It is very likely that if you make such a study that you get nonsignificant results due to the variation in your collectives. 4 Q. UESTIONS BY MR. THOMAS: 4 Q. Is it true, simple question, that there are no it's true that there are no clinical studies about which vou're aware  Page 371  1 that suggest that the design of the Prolene® material really is better than the outcome. But a we discussed 4 the study that you get nonsignificant results due to the variation in your collectives.  QUESTIONS BY MR. THOMAS: 4 that suggest that the design of the Prolene® mesh increases the risk of injury to a patient over in the treatment of stress urinary incontinence over a larger pore, lighter-weight mesh; is that true?  BRACH THEMENTESS: It isn't true  BRACH THEMENTESS: It isn't true  BRACH THE				
13 QUESTIONS BY MR. THOMAS: 14 Q. Okay. Is it your testimony 15 that you need to go to the specific 16 literature to learn what may be the 17 consequences of the use of mesh for the 18 treatment of stress urinary incontinence? 19 A. You have to include it into this. 20 well. You have to include it into this. 21 Q. What literature have you 22 considered to understand the complications 23 which arise from the use of mesh in the 24 treatment of stress urinary incontinence? 25 which arise from the use of mesh in the 26 treatment of stress urinary incontinence? 27 Page 371 2 A. I'm not able to give you a list 2 of all of the documents I've downloaded 3 during the past years. I regularly are 4 looking to the literature, and I know it's 5 hundreds of documents every week are coming, 6 some new. So, yeah, several. I looked at 7 several of them. 8 Q. Can you tell me one? 9 A. One of these publications? 9 A. One of these publications? 10 Q. Yes, just one. 11 A. Sling. As I told you, it's the 11 NICE meta-analysis. 12 Q. Okay. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published this year. There has been several studies 16 comparing the textile properties. 17 into outcome. But as we discussed yesterday, clinical studies are very ilimited in clarifying whether one material really is better than the other. 16 limited in clarifying whether one material really is better than the other. 17 other. It is very likely that if you make such a study that you get nonsignificant results due to the variation in your collectives. 20 Vestitons BY MR. THOMAS: 21 Q. Is it true, simple question, that there are no it's true that there are no it's tru				
14				
that you need to go to the specific literature to learn what may be the consequences of the use of mesh for the treatment of stress urinary incontinence?  A. You have to consider this as well. You have to include it into this.  Q. What literature have you considered to understand the complications which arise from the use of mesh in the of all of the documents I've downloaded during the past years. I regularly are looking to the literature, and I know it's hundreds of documents every week are coming, so mew. So, yeah, several. I looked at several of them.  Q. Can you tell me one? A. One of these publications? Q. Yes, just one.  NICE meta-analysis. Q. Okay. A. That their it is as I told you, the AWMF, it is study for PVDF meshes from Norway that has been published this year. There has been several studies.  Iimited in clarifying whether one material really is better than the other. It is very likely that if you make such a study that you get make such a study that you get nonsignificant results due to the variation in your collectives.  Q. Lis it true, simple question, that there are no it's true that there are no clinical studies about which you're aware  Page 371  That suggest that the design of the Prolene® mesh increases the risk of injury to a mesh increases the risk of i				
16   literature to learn what may be the   17   consequences of the use of mesh for the   17   treatment of stress urinary incontinence?   18   make such a study that you get   18   make such as tudy that you get   18   make such as tudy that you get   18   make such as tudy that you get   18   19   10   10   10   10   10   10   10				
treatment of stress urinary incontinence?  18 make such a study that you get 19 A. You have to consider this as 20 well. You have to include it into this. 21 Q. What literature have you 22 considered to understand the complications 23 which arise from the use of mesh in the 24 treatment of stress urinary incontinence?  Page 371  A. I'm not able to give you a list 2 of all of the documents I've downloaded 3 during the past years. I regularly are 4 looking to the literature, and I know it's 5 hundreds of documents every week are coming, 6 some new. So, yeah, several. I looked at 7 several of them.  Q. Can you tell me one?  A. One of these publications?  Q. Yes, just one.  10 Q. Yes, just one.  11 A. That their it is as I 1 told you, the AWMF, it is study that you get 19 nonsignificant results due to the 20 variation in your collectives. 21 QUESTIONS BY MR. THOMAS: 22 Q. Is it true, simple question, 23 that there are no it's true that there are 24 no clinical studies about which you're aware  Page 371  1 that suggest that the design of the Prolene® 2 mesh increases the risk of injury to a 2 patient over in the treatment of stress 2 urinary incontinence over a larger pore, 3 lighter-weight mesh; is that true? 4 MR. ANDERSON: Objection. 4 Asked and answered again. 4 HE WITNESS: It isn't true 4 because you didn't reduce it to the 2 pelvic floor. So if you made it in 2 QUESTIONS BY MR. THOMAS: 2 QUESTIONS BY MR. THOMAS: 3 QUESTIONS BY MR. THOMAS: 4 A. You just asked me if I'm 5 told you, the AWMF, it is study for PVDF 5 meshes from Norway that has been published 17 this year. There has been several studies 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.		•		• •
treatment of stress urinary incontinence?  18				
19				
well. You have to include it into this.  Q. What literature have you  considered to understand the complications which arise from the use of mesh in the  treatment of stress urinary incontinence?  Page 371  A. I'm not able to give you a list of all of the documents I've downloaded during the past years. I regularly are looking to the literature, and I know it's hundreds of documents every week are coming, some new. So, yeah, several. I looked at several of them.  Q. Can you tell me one?  A. One of these publications?  Q. Is it true, simple question, that there are no it's true that there are and clinical studies about which you're aware  Page 371  that suggest that the design of the Prolene® mesh increases the risk of injury to a patient over in the treatment of stress urinary incontinence over a larger pore, lighter-weight mesh; is that true?  MR. ANDERSON: Objection.  Asked and answered again.  THE WITNESS: It isn't true because you didn't reduce it to the pelvic floor. So if you made it in general Q. Okay.  A. That their it is as I  VICE meta-analysis.  Q. Okay.  A. That their it is as I  told you, the AWMF, it is study for PVDF meshes from Norway that has been published this year. There has been several studies  The wind there are on it's true that there are on it's true that there are a no clinical studies about which you're aware  Page 371  that suggest that the design of the Prolene® mesh increases the risk of injury to a patient over in the treatment of stress urinary incontinence over a larger pore, lighter-weight mesh; is that true?  MR. ANDERSON: Objection.  Asked and answered again.  THE WITNESS: It isn't true because you didn't reduce it to the pelvic floor. So if you made it in general QUESTIONS BY MR. THOMAS:  Q. Oh, I think I did. A. You just asked me if I'm correct. If there are clinical studies  time the reare of inical studies of the reare analysis.  Q. Oh, I think I did. A. You just asked me if I'm is comparison to heavy-weight or I missed it. So a general, th				
Q. What literature have you considered to understand the complications which arise from the use of mesh in the treatment of stress urinary incontinence?  Page 371  A. I'm not able to give you a list of all of the documents I've downloaded dowing the past years. I regularly are looking to the literature, and I know it's hundreds of documents every week are coming, some new. So, yeah, several. I looked at several of them.  Q. Can you tell me one? lighter-weight mesh; is that true?  A. One of these publications? look of A. Sling. As I told you, it's the lat suggest that the design of the Prolene® mesh increases the risk of injury to a patient over in the treatment of stress urinary incontinence over a larger pore, lighter-weight mesh; is that true?  MR. ANDERSON: Objection.  Asked and answered again.  THE WITNESS: It isn't true because you didn't reduce it to the pelvic floor. So if you made it in general  Q. Yes, just one.  NICE meta-analysis.  Q. Okay.  A. That their it is as I look you, the AWMF, it is study for PVDF meshes from Norway that has been published for the properties.  D. Okay.  A. That their result is study for PVDF this year. There has been several studies to meshes from Norway that has been published this year. There has been several studies comparing the textile properties.				
considered to understand the complications which arise from the use of mesh in the treatment of stress urinary incontinence?  Page 371  A. I'm not able to give you a list of all of the documents I've downloaded during the past years. I regularly are looking to the literature, and I know it's hundreds of documents every week are coming, several of them.  Q. Can you tell me one? A. One of these publications? Q. Yes, just one.  NICE meta-analysis. Q. Okay. A. That their it is as I that suggest that the design of the Prolene® mesh increases the risk of injury to a patient over in the treatment of stress urinary incontinence over a larger pore, lighter-weight mesh; is that true?  MR. ANDERSON: Objection. Asked and answered again. THE WITNESS: It isn't true because you didn't reduce it to the pelvic floor. So if you made it in general QUESTIONS BY MR. THOMAS: Q. Oh, I think I did. A. You just asked me if I'm tody you, the AWMF, it is study for PVDF meshes from Norway that has been published this year. There has been several studies comparing the textile properties.  A. I'm not able to give you a list that there are no it's true that there are no clinical studies about which you're aware  Page 371  that suggest that the design of the Prolene® mesh increases the risk of injury to a patient over in the treatment of stress urinary incontinence over a larger pore, lighter-weight mesh; is that true?  MR. ANDERSON: Objection.  A sked and answered again.  THE WITNESS: It isn't true because you didn't reduce it to the pelvic floor. So if you made it in general QUESTIONS BY MR. THOMAS:  Q. Oh, I think I did. A. You just asked me if I'm correct. If there are clinical studies showing that Prolene® has more complications in comparison to heavy-weight or I missed it. So a general, there are clinical studies.				
which arise from the use of mesh in the treatment of stress urinary incontinence?  Page 371  A. I'm not able to give you a list of all of the documents I've downloaded during the past years. I regularly are looking to the literature, and I know it's hundreds of documents every week are coming, some new. So, yeah, several. I looked at several of them.  Q. Can you tell me one? A. One of these publications?  A. Sling. As I told you, it's the  I. A. Sling. As I told you, it's the told you, the AWMF, it is study for PVDF meshes from Norway that has been published that there are no it's true that there are no clinical studies about which you're aware  page 371  that there are no it's true that there are no clinical studies about which you're aware  page 371  that there are no it's true that there are no clinical studies about which you're aware  page 371  that there are no it's true that there are no clinical studies about which you're aware  page 371  that there are no it's true that there are no clinical studies about which you're aware  page 371  that there are no it's true that there are no clinical studies about which you're aware  page 371  that there are no it's true that there are no clinical studies about which you're aware  page 371  that there are no it's true that there are no clinical studies about which you're aware  page 371  that there are no it's true baseout which you're aware  page 371  that there are no it's true baseout which you're aware  page 371  that suggest that the design of the Prolene® mesh increases the risk of injury to a  patient over in the treatment of stress  urinary incontinence over a larger pore,  lighter-weight mesh; is that true?  A. R. An Dte treatment of stress  urinary incontinence over a larger pore,  lighter-weight mesh; is that true?  A. R. An Dte treatment of stress  urinary incontinence over a larger pore,  lighter-weight mesh; is that true?  A. A. A. One of these publications?  2. W.R. ANDERSON: Objection.  Asked and answered again.  3.				
treatment of stress urinary incontinence?  Page 371  A. I'm not able to give you a list of all of the documents I've downloaded owing the past years. I regularly are looking to the literature, and I know it's hundreds of documents every week are coming, several of them.  Q. Can you tell me one? A. One of these publications?  Q. Yes, just one.  NICE meta-analysis.  Q. Okay.  A. That their it is as I told you, the AWMF, it is study for PVDF meshes from Norway that has been published meshes from Norway that has been published to fall of the documents every wou a list that suggest that the design of the Prolene® mesh increases the risk of injury to a patient over in the treatment of stress urinary incontinence over a larger pore, lighter-weight mesh; is that true?  MR. ANDERSON: Objection.  Asked and answered again.  THE WITNESS: It isn't true because you didn't reduce it to the pelvic floor. So if you made it in general  QUESTIONS BY MR. THOMAS:  Q. Oh, I think I did.  A. You just asked me if I'm correct. If there are clinical studies showing that Prolene® has more complications in comparison to heavy-weight or I missed it.  So a general, there are clinical studies.		<u> </u>		
Page 371  A. I'm not able to give you a list  of all of the documents I've downloaded  during the past years. I regularly are  looking to the literature, and I know it's  hundreds of documents every week are coming,  some new. So, yeah, several. I looked at  several of them.  Q. Can you tell me one?  A. One of these publications?  Q. Yes, just one.  NICE meta-analysis.  Q. Okay.  A. That their it is as I  told you, the AWMF, it is study for PVDF  meshes from Norway that has been published  that suggest that the design of the Prolene®  mesh increases the risk of injury to a  patient over in the treatment of stress  urinary incontinence over a larger pore, lighter-weight mesh; is that true?  MR. ANDERSON: Objection.  Asked and answered again.  THE WITNESS: It isn't true  because you didn't reduce it to the pelvic floor. So if you made it in general  QUESTIONS BY MR. THOMAS:  Q. Oh, I think I did.  A. You just asked me if I'm  correct. If there are clinical studies  showing that Prolene® has more complications in comparison to heavy-weight or I missed it.  So a general, there are clinical studies.				
2 of all of the documents I've downloaded 3 during the past years. I regularly are 4 looking to the literature, and I know it's 5 hundreds of documents every week are coming, 6 some new. So, yeah, several. I looked at 7 several of them. 8 Q. Can you tell me one? 9 A. One of these publications? 10 Q. Yes, just one. 11 A. Sling. As I told you, it's the 12 NICE meta-analysis. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties. 2 mesh increases the risk of injury to a 3 patient over in the treatment of stress 4 urinary incontinence over a larger pore, 5 lighter-weight mesh; is that true? 6 MR. ANDERSON: Objection. 7 Asked and answered again. 8 THE WITNESS: It isn't true 9 because you didn't reduce it to the 10 pelvic floor. So if you made it in 11 general 12 QUESTIONS BY MR. THOMAS: 13 Q. Oh, I think I did. 14 A. You just asked me if I'm 15 correct. If there are clinical studies 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.	21		21	Page 373
2 of all of the documents I've downloaded 3 during the past years. I regularly are 4 looking to the literature, and I know it's 5 hundreds of documents every week are coming, 6 some new. So, yeah, several. I looked at 7 several of them. 8 Q. Can you tell me one? 9 A. One of these publications? 10 Q. Yes, just one. 11 A. Sling. As I told you, it's the 12 NICE meta-analysis. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties. 2 mesh increases the risk of injury to a 3 patient over in the treatment of stress 4 urinary incontinence over a larger pore, 5 lighter-weight mesh; is that true? 6 MR. ANDERSON: Objection. 7 Asked and answered again. 8 THE WITNESS: It isn't true 9 because you didn't reduce it to the 10 pelvic floor. So if you made it in 11 general 12 QUESTIONS BY MR. THOMAS: 13 Q. Oh, I think I did. 14 A. You just asked me if I'm 15 correct. If there are clinical studies 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.	1	A. I'm not able to give you a list	1	that suggest that the design of the Prolene®
3 during the past years. I regularly are 4 looking to the literature, and I know it's 5 hundreds of documents every week are coming, 6 some new. So, yeah, several. I looked at 7 several of them. 8 Q. Can you tell me one? 9 A. One of these publications? 10 Q. Yes, just one. 11 A. Sling. As I told you, it's the 12 NICE meta-analysis. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties. 3 patient over in the treatment of stress 4 urinary incontinence over a larger pore, 5 lighter-weight mesh; is that true? 6 MR. ANDERSON: Objection. 7 Asked and answered again. 8 THE WITNESS: It isn't true 9 because you didn't reduce it to the 10 pelvic floor. So if you made it in 11 general 12 QUESTIONS BY MR. THOMAS: 13 Q. Oh, I think I did. 14 A. You just asked me if I'm 15 correct. If there are clinical studies 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.				
4 looking to the literature, and I know it's 5 hundreds of documents every week are coming, 6 some new. So, yeah, several. I looked at 7 several of them. 8 Q. Can you tell me one? 9 A. One of these publications? 10 Q. Yes, just one. 11 A. Sling. As I told you, it's the 12 NICE meta-analysis. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties. 4 urinary incontinence over a larger pore, lighter-weight mesh; is that true? 6 MR. ANDERSON: Objection. 7 Asked and answered again. 8 THE WITNESS: It isn't true 9 because you didn't reduce it to the pelvic floor. So if you made it in general 10 QUESTIONS BY MR. THOMAS: 11 A. You just asked me if I'm 15 correct. If there are clinical studies 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.				
5 hundreds of documents every week are coming, 6 some new. So, yeah, several. I looked at 7 several of them. 8 Q. Can you tell me one? 9 A. One of these publications? 10 Q. Yes, just one. 11 A. Sling. As I told you, it's the 12 NICE meta-analysis. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties. 5 lighter-weight mesh; is that true? 6 MR. ANDERSON: Objection. 7 Asked and answered again. 7 HE WITNESS: It isn't true 9 because you didn't reduce it to the 10 pelvic floor. So if you made it in 11 general 12 QUESTIONS BY MR. THOMAS: 13 Q. Oh, I think I did. 14 A. You just asked me if I'm 15 correct. If there are clinical studies 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.				*
6 some new. So, yeah, several. I looked at 7 several of them. 8 Q. Can you tell me one? 9 A. One of these publications? 10 Q. Yes, just one. 11 A. Sling. As I told you, it's the 12 NICE meta-analysis. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties.  6 MR. ANDERSON: Objection. 7 Asked and answered again. 8 THE WITNESS: It isn't true 9 because you didn't reduce it to the 10 pelvic floor. So if you made it in 11 general 12 QUESTIONS BY MR. THOMAS: 13 Q. Oh, I think I did. 14 A. You just asked me if I'm 15 correct. If there are clinical studies 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.				
7 Several of them. 8 Q. Can you tell me one? 9 A. One of these publications? 10 Q. Yes, just one. 11 A. Sling. As I told you, it's the 12 NICE meta-analysis. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties. 7 Asked and answered again. 8 THE WITNESS: It isn't true 9 because you didn't reduce it to the 10 pelvic floor. So if you made it in 11 general 12 QUESTIONS BY MR. THOMAS: 13 Q. Oh, I think I did. 14 A. You just asked me if I'm 15 correct. If there are clinical studies 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.		•		
8 Q. Can you tell me one? 9 A. One of these publications? 10 Q. Yes, just one. 11 A. Sling. As I told you, it's the 12 NICE meta-analysis. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties.  8 THE WITNESS: It isn't true 9 because you didn't reduce it to the 10 pelvic floor. So if you made it in 11 general 12 QUESTIONS BY MR. THOMAS: 13 Q. Oh, I think I did. A. You just asked me if I'm 15 correct. If there are clinical studies 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.				ŭ
9 A. One of these publications? 10 Q. Yes, just one. 11 A. Sling. As I told you, it's the 12 NICE meta-analysis. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties.  9 because you didn't reduce it to the 10 pelvic floor. So if you made it in 11 general 12 QUESTIONS BY MR. THOMAS: 13 Q. Oh, I think I did. 14 A. You just asked me if I'm 15 correct. If there are clinical studies 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.			l .	
10 Q. Yes, just one.  11 A. Sling. As I told you, it's the 12 NICE meta-analysis. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties. 10 pelvic floor. So if you made it in 11 general 12 QUESTIONS BY MR. THOMAS: 13 Q. Oh, I think I did. 14 A. You just asked me if I'm 15 correct. If there are clinical studies 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.			9	
11 A. Sling. As I told you, it's the 12 NICE meta-analysis. 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties. 11 general 12 QUESTIONS BY MR. THOMAS: 13 Q. Oh, I think I did. 14 A. You just asked me if I'm 15 correct. If there are clinical studies 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.		*		
12 QUESTIONS BY MR. THOMAS: 13 Q. Okay. 14 A. That their it is as I 15 told you, the AWMF, it is study for PVDF 16 meshes from Norway that has been published 17 this year. There has been several studies 18 comparing the textile properties. 19 QUESTIONS BY MR. THOMAS: 10 Q. Oh, I think I did. 11 A. You just asked me if I'm 12 QUESTIONS BY MR. THOMAS: 13 Q. Oh, I think I did. 14 A. You just asked me if I'm 15 correct. If there are clinical studies 16 showing that Prolene® has more complications 17 in comparison to heavy-weight or I missed it. 18 So a general, there are clinical studies.				
13Q. Okay.13Q. Oh, I think I did.14A. That their it is as I14A. You just asked me if I'm15told you, the AWMF, it is study for PVDF15correct. If there are clinical studies16meshes from Norway that has been published16showing that Prolene® has more complications17this year. There has been several studies17in comparison to heavy-weight or I missed it.18So a general, there are clinical studies.		· · · · · · · · · · · · · · · · · · ·		
A. That their it is as I  told you, the AWMF, it is study for PVDF  meshes from Norway that has been published this year. There has been several studies  comparing the textile properties.  A. You just asked me if I'm  correct. If there are clinical studies showing that Prolene® has more complications in comparison to heavy-weight or I missed it.  So a general, there are clinical studies.		•		
told you, the AWMF, it is study for PVDF meshes from Norway that has been published this year. There has been several studies comparing the textile properties.  15 correct. If there are clinical studies showing that Prolene® has more complications in comparison to heavy-weight or I missed it. So a general, there are clinical studies.				
meshes from Norway that has been published this year. There has been several studies comparing the textile properties.  16 showing that Prolene® has more complications in comparison to heavy-weight or I missed it.  18 So a general, there are clinical studies.				
this year. There has been several studies comparing the textile properties.  17 in comparison to heavy-weight or I missed it. So a general, there are clinical studies.				
18 comparing the textile properties. 18 So a general, there are clinical studies.		•		_
119 O. Are there any clinical studies 119 For the lise as sling. I don't know any	19	Q. Are there any clinical studies	19	For the use as sling, I don't know any.
20 about which you're aware that suggest that 20 Q. Okay. So just to make sure		The state of the s		
21 the design of the Prolene® mesh increases the 21 we're clear. For the use of slings, mesh				
22 risk of injury to a patient over a larger 22 slings, in the treatment of stress urinary				
23 pore, lighter-weight mesh? 23 incontinence, you're unaware of any clinical				
24 MR. ANDERSON: Objection again. 24 studies that show that the use of Prolene®				

9 (Pages 370 to 373)

	Page 374		Page 376
1	mesh increases the risk of injury to a	1	get objective analysis of this pore
2	patient in the treatment of stress urinary	2	distribution. To make it easier to
3	incontinence over a larger pore,	3	understand what was found in histology, to
4	lighter-weight mesh; is that true?	4	make it easier to understand what are the
5	MR. ANDERSON: Objection.	5	consequences if you change something of the
6	Asked and answered.	6	textile construction, what is the consequence
7	THE WITNESS: That is true.	7	to the pore sizes and the distribution of the
8	QUESTIONS BY MR. THOMAS:	8	pores, therefore, we made this machine or we
9	Q. Okay. Doctor, on page 2 of	9	developed this machine together with
10	your report, you continue and say, "The	10	Professor Mühl and it was able to get clear
11	Prolene® mesh in TVT® is a small pore mesh."	11	images of a mesh construction and if you are
12		12	· ·
13	How big is the pore in TVT®	13	using the textile porosity as before, you get this distribution.
14	used for the treatment of stress urinary incontinence?	14	The next decision has to be how
15		15	
	A. This is this is a question	I	to compare distributions to define which is
16	that is that has to be explained in detail	16	better than the other. And it is
17	from various aspects. It is insufficient to	17	statistically, scientifically it is not easy
18	just make a measure in one dimension and say	18	to make a reliable comparison of
19	this is a pore.	19	distributions and, therefore, we decided to
20	In the '90s, we made with the	20	make a cutoff, to define a cutoff because we
21	VYPRO mesh with 3, 4, 5 millimeters of pores	21	have seen at various histological sections
22	roughly when you make these measurements. So	22	that there may be a minimum pore size that is
23	these are considered really as large pores.	23	increasing the risk for this bridging. It
24	There are others that are from the	24	has been with the Marlex. It has been done
	Page 375		Page 377
1	microscopical view can be regarded as small	1	for the first time with the Marlex, and we
2	pores. So to make a precise measurement of	2	have somewhere in your documents there is
3	the pore size or the distribution of the	3	a PowerPoint slide with a distribution and
4	pores, it was a problem for a long time.	4	then there is on the left side, there is a
5	We first started in 2000, I	5	distribution for the Marlex and there we
6	think, for the first time that we tried to	6	marked in between 600 and 800 microns that we
7	figure out that it is a distribution, that	7	saw and we measured the distance of the
8	every mesh has some smaller pores, some	8	filaments that we saw that below this border
9	larger pores. So one specific value yeah,	9	of 600, 800 with the Marlex and you have this
10	figure and value of a pore, this does not	10	bridging.
11	reflect the reality of a mesh construction.	11	Later on, 2003, 2002, we took
12	So you have these different pore sizes in	12	as a limit as a cutoff to separate the
13	every mesh.	13	meshes with low risk and high risk by 1
14		14	millimeter because we then had the values of
	And then we got aware that if		minimized secares we men mad the values of
15	And then we got aware that if you look to the histology and not to the	15	
15 16	you look to the histology and not to the		the experiments that has been published by Conze where we measured it in Aachen.
	you look to the histology and not to the foreign body reaction around the filaments	15	the experiments that has been published by Conze where we measured it in Aachen.
16	you look to the histology and not to the	15 16	the experiments that has been published by Conze where we measured it in Aachen. But at the beginning, we
16 17	you look to the histology and not to the foreign body reaction around the filaments but to the pores inside, then you see the differences that in the VYPRO and the	15 16 17	the experiments that has been published by Conze where we measured it in Aachen. But at the beginning, we noticed that there is an impact of the
16 17 18	you look to the histology and not to the foreign body reaction around the filaments but to the pores inside, then you see the differences that in the VYPRO and the ULTRAPRO <sup>TM</sup> , you don't have this bridging and	15 16 17 18	the experiments that has been published by Conze where we measured it in Aachen. But at the beginning, we noticed that there is an impact of the polymer so we separated for PVDF and PP. Of
16 17 18 19	you look to the histology and not to the foreign body reaction around the filaments but to the pores inside, then you see the differences that in the VYPRO and the ULTRAPRO <sup>TM</sup> , you don't have this bridging and there are, if the filaments are coming closer	15 16 17 18 19	the experiments that has been published by Conze where we measured it in Aachen. But at the beginning, we noticed that there is an impact of the
16 17 18 19 20 21	you look to the histology and not to the foreign body reaction around the filaments but to the pores inside, then you see the differences that in the VYPRO and the ULTRAPRO <sup>TM</sup> , you don't have this bridging and there are, if the filaments are coming closer together, then you have these pores filled by	15 16 17 18 19 20 21	the experiments that has been published by Conze where we measured it in Aachen. But at the beginning, we noticed that there is an impact of the polymer so we separated for PVDF and PP. Of course, there are a lot of other impact factors that can do it.
16 17 18 19 20 21 22	you look to the histology and not to the foreign body reaction around the filaments but to the pores inside, then you see the differences that in the VYPRO and the ULTRAPRO <sup>TM</sup> , you don't have this bridging and there are, if the filaments are coming closer together, then you have these pores filled by scar tissue. So there seems to be a	15 16 17 18 19 20 21 22	the experiments that has been published by Conze where we measured it in Aachen. But at the beginning, we noticed that there is an impact of the polymer so we separated for PVDF and PP. Of course, there are a lot of other impact factors that can do it. So the question what is small
16 17 18 19 20 21	you look to the histology and not to the foreign body reaction around the filaments but to the pores inside, then you see the differences that in the VYPRO and the ULTRAPRO <sup>TM</sup> , you don't have this bridging and there are, if the filaments are coming closer together, then you have these pores filled by	15 16 17 18 19 20 21	the experiments that has been published by Conze where we measured it in Aachen. But at the beginning, we noticed that there is an impact of the polymer so we separated for PVDF and PP. Of course, there are a lot of other impact factors that can do it.

10 (Pages 374 to 377)

	Page 378		Page 380
1	figure. If you take the extremes, the	1	A. It depends from your definition
2	ULTRAPRO <sup>TM</sup> , the VYPRO, was a pore of 3 to	2	what you're thinking of as a pore size. What
3	5-millimeter. If you made a linear	3	is of course, you can make images of the
4	measurement there with all of the	4	pore area so first of all, you have to
5	limitations, all restrictions, please don't	5	define what is your meaning of pore size, in
6	stick me to this number 3 to 5-millimeter.	6	what context you want to have this. General
7	It's just a shortening of this. This is low	7	finding.
8	risk for bridging, and whereas, very small	8	Q. Doctor, are you I am sorry,
9	pores has a high risk of bridging. That is	9	I didn't mean to interrupt you.
10	the message.	10	A. Yeah.
11	Q. Doctor, have you ever attempted	11	Q. Doctor, are you aware of any
12	to physically measure the pore in the	12	standard that tells you or Ethicon how to
13	Prolene® mesh used in TVT® for stress urinary	13	measure pore size?
14	incontinence repair?	14	A. I think or the the best
15	A. Whether we made a measurement	15	solution to get an idea or to try an
16	of the Prolene® mesh?	16	objective measurement to make a
17	Q. Yes.	17	characterization of textile structures by the
18	A. Dr. Mühl did it.	18	use of pores, this is done in this
19	(Klinge Exhibit 20 marked for	19	publication.
20	identification.)	20	Q. Okay. Other than the Mühl
21	QUESTIONS BY MR. THOMAS:	21	publication, Exhibit Number 20 that we've
22	Q. And I'm not and just for the	22	talked about before, are you aware of any
23	record, what you're talking about is Exhibit	23	standard promulgated by any regulatory,
24	Number 20, the article that you coauthored	24	public health authority or company that tells
	Page 379		Page 381
1	with Dr. Mühl in 2007, "The New Objective	1	you or Ethicon how to measure its pore size?
2	Measurements to Characterize the Porosity of	2	A. I know there are some there
3	Textile Implants."	3	has been some publications related to the
4	Is that correct?	4	textile porosity. How to make the textile
5	A. Yes.	5	porosity in a two-dimensional way. There are
6	Q. My question is in the 1990s	6	some there are maybe some experimental
7	when you're doing your experiments, did you	7	other attempts to grasp the problem of pores
8	ever measure the pore size of the TVT® mesh	8	to describe this. But there is, of course, I
9	used strike that.	9	don't know any official standard showing you
10	In the 1990s when you were	10	have to do it like this.
11	studying first generation Prolene® mesh,	11	Q. In the '90s when you were doing
12	which you call old Prolene®, did you ever	12	your own studies, you measured them in a
13	measure the pore sizes?	13	linear fashion; is that true?
14	A. The pore sizes in the '90s have	14	A. At the beginning, yes.
15	been done first by just making linear	15	Q. Okay. And tell me how you did
16	measurements. We know we all know that	16	that. What points in the pore did you
17	this is not accurate to give a good	17	measure?
18	reflection of the pore size, but at that	18	A. As I remember, we had a visual
19	time, it was the way we did it, and the next	19	impression what may be the mean distance in
20	thing we tried to do is the textile porosity.	20	the pore. Not looking what is the farest
21	So it is impossible. It is still today	21	distance, what is the shortest, but what may
22	impossible to measure a pore size.	22	be the mean roughly.
23	Q. Okay. Still today impossible	23	But, again, the purpose at that
24	to measure a pore size, correct?	24	time was to give a hint to the reader, to

11 (Pages 378 to 381)

	Page 382		Page 384
1	show the difference between 3 millimeters and	1	Q. At any time in your research
2	.3 millimeters. And, therefore, this gives a	2	from 1993 to the present, in your experience,
3	good impression that the textile construction	3	was it ever appropriate to describe Prolene®
4	was different.	4	as a large pore macroporous mesh?
5	Q. Before VYPRO, was there	5	A. It is in contrast. If you're
6	anything in the literature about	6	looking to our experimental publications,
7	light-weight strike that.	7	there we took the Prolene® mesh in our
8	Before VYPRO, was there	8	experiments as a control for a mesh that is
9	anything about a comparison of large pore to	9	usually bridging, that induces usually an
10	small pore in the literature?	10	intense inflammatory and fibrotic reaction.
11	A. I'm not aware of it, no.	11	That was our control for many of these
12	Q. Before VYPRO, was Prolene®	12	experiments.
13	known as a large pore mesh?	13	And on the other end, we really
14	A. These words were not it was	14	had some large pores, light-weight mesh
15	not a discussion. At the beginning of the	15	materials, but the prototype of a
16	'90s, you already had the Mersilene.	16	heavy-weight, small pore meshes, that has
17	Mersilene is a mesh with a very low weight.	17	been Marlex and Prolene®.
18	You had the Prolene® with very high weight,	18	Q. My question, Doctor, is a very
19	and there hasn't been any discussion about	19	simple one and I'm trying to understand
20	the different textile characteristics. I	20	whether based on your 20 years of experience
21	think that is what we introduced. If you	21	in this field, at any time during that
22	look to the literature what has been	22	20 years whether the state of knowledge about
23	published until '99 with the search for	23	mesh design was such that it was appropriate
24	meshes, you will hardly find any good data up	24	to describe first generation 6-mil Prolene®
	Page 383		Page 385
1	to there. It's a dozen experimental studies	1	mesh as large pore and macroporous?
2	until this and then it's going up.	2	MR. ANDERSON: Objection to
3	Q. Was the first generation 6-mil	3	form.
4	Prolene® mesh used for hernia repair, which	4	THE WITNESS: No. No. It
5	you refer to as old Prolene®, ever described	5	is
6	in the literature as large pore macroporous	6	QUESTIONS BY MR. THOMAS:
7	mesh?	7	Q. You're familiar with the Amid
8	A. In what before 1995, that	8	classification?
9	has not been the wording for to describe a	9	A. Uh-huh.
10	experimental setting there. Yeah, later on,	10	Q. Is that "yes"?
11	I know that there is some of the documents	11	A. Yes. Yes. Sorry.
12	where we took over I think ourselves took	12	Q. And you know under the Amid
13	over some measurements provided by the	13	classification that Prolene® is a Class I
14	manufacturer and said or took it in and	14	mesh? Is that "yes"?
15	mentioned it as 1.2 millimeter, the pore	15	A. Yes, I know it, but I have to
16	size.	16	explain this is not fair because now we are
17	So, but, yeah, as we discussed	17	switching to different definitions of large
18	already, it is not sufficient to give a real	18	pore.
19	impression of pore. It's too difficult.	19	Q. Okay.
20	Q. Doctor, we spent a lot of time	20	A. I
21	yesterday talking about the progress in your	21	Q. Can I
22	understanding about the design of meshes	22	A. From our work, it is very clear
23	beginning in the party in Christmas in 1993?	23	what large pore is. That is a large pore.
24	A. Uh-huh.	24	The consequence of a large pore that you have

12 (Pages 382 to 385)

	Page 386		Page 388
1	a low risk for bridging. That is the message	1	top (AMS, American Medical Systems)
2	of all our work, and this shouldn't be put	2	describing the different meshes tested in
3	together with the definition of large pore in	3	this study.
4	the Amid classification because he has a	4	Have you looked at this table
5	different aim and purpose to do so.	5	before?
6	So it is mixing up two	6	A. Yes.
7	different things and it is increasing the	7	Q. And there are six different
8	confusion that everywhere happens.	8	types of meshes that are used for the
9	Q. You've talked about the Amid	9	treatment of stress urinary incontinence; is
10	classification at length in other depositions	10	that correct?
11	and I'm not going to explore that again, but	11	A. That is correct.
12	feel free	12	Q. And the authors in the Moalli
13	A. Me neither.	13	paper have a category for mesh thickness,
14	(Klinge Exhibit 21 marked for	14	correct?
15	identification.)	15	A. Yes.
16	QUESTIONS BY MR. THOMAS:	16	Q. And mesh thickness is exactly
17	Q. Doctor, I've handed you what's	17	what it says, it's just how thick the mesh
18	been marked as Exhibit 21.	18	is?
19	Exhibit 21 is a	19	A. Yes.
20	MR. ANDERSON: Excuse me,	20	Q. Then it has pore size and it
21	Counsel, can you tell me what the F	21	shows the pore sizes for each of these meshes
22	mesh is? Mine is cut off.	22	used for the treatment of TVT®, and you
23	MR. THOMAS: Yeah, mine is too.	23	understand that Gynecare is the TVT® mesh,
24	I was just going to say that for the	24	correct?
	Page 387		Page 389
1	record, but I can't, but I'll get them	1	A. Yes.
2	for you.	2	Q. And the Gynecare mesh is shown
3	QUESTIONS BY MR. THOMAS:	3	as having a pore size of 1,379 microns,
4	Q. Exhibit 21 a journal article in	4	correct?
5	the International Urogynecology Journal,	5	A. It is written here, but we
6	volume 19, number 5, May 2008, it's titled	6	pointed out, I think, very extensively that
7	"Tensile Properties of Five Commonly Used	7	the number of 1,379 microns is a measurement
8	Midurethral Slings Relative to the TVT®."	8	within the textile mesh, but it does not
9	You cited this article in your	9	reflect the textile characteristic in regard
10	paper, haven't you? Do you remember that?	10	to pores and porosity because you always have
11	A. Cited in what	11	a distribution.
12	Q. In your report?	12	But you see still here in the
13	A. Yes. Yes. It's very nice,	13	year 2008, it was still used there, but this
14	very interesting study.	14	is not what is the relevant information to
15	Q. And this study compares the	15	predict the tissue reaction there.
16	tensile properties of five different slings	16	Q. Do you view
17	against the Johnson & Johnson TVT® sling,	17	A. So it's not relevant. It's not
18	correct?	18	really relevant.
19	A. The textile properties, yeah.	19	Q. Okay. Is it inappropriate from
20	Q. Okay. I want you to turn to	20	a scientific perspective for the authors in
21	page 657 of Exhibit 21, to Table 1.	21	the Moalli study, Exhibit 21, to regard pore
22	And Table 1 shows, "The textile	22	size in this fashion?
23	properties (including loaded failure)	23	A. No, it is no. It is a
25	properties (mercaning rounded randies)		

13 (Pages 386 to 389)

	Page 390		Page 392
1	when they were not aware of the problems of	1	A. No.
2	this. You cannot discuss every parameter in	2	Q. Are you aware of any other mesh
3	detail in every manuscript, otherwise, you	3	marketed in the United States for the
4	so every manuscript is a comprise. You can	4	treatment of stress urinary incontinence
5	present some data.	5	other than the ones listed in Exhibit 21?
6	But in this litigation, we're	6	A. Aware in the meaning that I
7	sitting here and discussing about the pores	7	know that there are several others. I'm
8	of the Prolene® and when you cited this	8	not I'm not able to present the total list
9	document as proof that Prolene® is a mesh	9	of all possible sling materials there.
10		10	Q. Okay. The PVDF mesh for the
11	with pore size of more than 1,000 microns, that is that is not relevant. It is a	11	
12		12	treatment of stress urinary incontinence is
13	it is a paper, it is a manuscript and they	13	not available in the United States.
	did the best to take the information they got		You agree with that?
14	there, but it doesn't help me for my opinion	14	A. To my knowledge, it is correct.
15	whether it's a small pore or large pore.	15	Q. And the PVDF mesh from FEG
16	That is the fact that has to be clear, I	16	that's used for the treatment of stress
17	think.	17	urinary incontinence has not been approved by
18	Q. I understand that. I actually	18	the United States Food and Drug
19	am going to use this for a whole different	19	Administration.
20	reason than you think.	20	Do you agree with that?
21	A. I'm not sure.	21	A. It is yeah, to my knowledge,
22	Q. I know that, but that's why I	22	it is the fact. But I'm not sure whether
23	get to ask the questions.	23	they really sent it to them to have it
24	A. And I have to be concerned.	24	checked.
	Page 391		Page 393
			rage 373
1	Q. No, you don't.	1	Q. I understand.
2	Q. No, you don't. So have you looked at the mesh	1 2	
	The state of the s	l .	Q. I understand.
2	So have you looked at the mesh	2	<ul><li>Q. I understand.</li><li>A. Or whether they didn't do it.</li></ul>
2 3	So have you looked at the mesh of Boston Scientific used in the treatment of	2 3	<ul><li>Q. I understand.</li><li>A. Or whether they didn't do it.</li><li>Q. I don't know whether they've</li></ul>
2 3 4	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?	2 3 4	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but
2 3 4 5	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific	2 3 4 5	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is
2 3 4 5 6	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.	2 3 4 5 6	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference.
2 3 4 5 6 7	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?	2 3 4 5 6 7	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me
2 3 4 5 6 7 8	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.	2 3 4 5 6 7 8	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used
2 3 4 5 6 7 8 9	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:	2 3 4 5 6 7 8	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary
2 3 4 5 6 7 8 9	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh	2 3 4 5 6 7 8 9	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore
2 3 4 5 6 7 8 9 10	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh manufactured by AMS for the treatment of	2 3 4 5 6 7 8 9 10	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that
2 3 4 5 6 7 8 9 10 11 12	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?  A. No.	2 3 4 5 6 7 8 9 10 11 12	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study? A. No.
2 3 4 5 6 7 8 9 10 11 12 13	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh	2 3 4 5 6 7 8 9 10 11 12 13	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study? A. No. Q. Why?
2 3 4 5 6 7 8 9 10 11 12 13 14 15	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by BARD for the treatment of	2 3 4 5 6 7 8 9 10 11 12 13 14	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study? A. No. Q. Why? A. Because the question what is
2 3 4 5 6 7 8 9 10 11 12 13 14	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by BARD for the treatment of stress urinary incontinence?	2 3 4 5 6 7 8 9 10 11 12 13	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study? A. No. Q. Why? A. Because the question what is the pore size, whether it's bigger than the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by BARD for the treatment of stress urinary incontinence?  A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study? A. No. Q. Why? A. Because the question what is the pore size, whether it's bigger than the other, it cannot be answered. You have this
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by BARD for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured?  A. No.  Q. Have you looked at the mesh	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study? A. No. Q. Why? A. Because the question what is the pore size, whether it's bigger than the other, it cannot be answered. You have this distribution. You have some pores bigger
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by BARD for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by BARD for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by Caldera for the treatment of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study? A. No. Q. Why? A. Because the question what is the pore size, whether it's bigger than the other, it cannot be answered. You have this distribution. You have some pores bigger than the others. You have to make the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by BARD for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by Caldera for the treatment of stress urinary incontinence?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study? A. No. Q. Why? A. Because the question what is the pore size, whether it's bigger than the other, it cannot be answered. You have this distribution. You have some pores bigger than the others. You have to make the testing or you have to figure out what is the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by BARD for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by Caldera for the treatment of stress urinary incontinence?  A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study? A. No. Q. Why? A. Because the question what is the pore size, whether it's bigger than the other, it cannot be answered. You have this distribution. You have some pores bigger than the others. You have to make the testing or you have to figure out what is the specific distribution of the various pore
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by BARD for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by Caldera for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by Caldera for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study? A. No. Q. Why? A. Because the question what is the pore size, whether it's bigger than the other, it cannot be answered. You have this distribution. You have some pores bigger than the others. You have to make the testing or you have to figure out what is the specific distribution of the various pore size and then when you want to make a cutoff,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?  MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?  THE WITNESS: No.  QUESTIONS BY MR. THOMAS:  Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by BARD for the treatment of stress urinary incontinence?  A. No.  Q. Have you looked at the mesh manufactured by Caldera for the treatment of stress urinary incontinence?  A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. I understand. A. Or whether they didn't do it. Q. I don't know whether they've asked either, but A. But this is I think this is a major difference. Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study? A. No. Q. Why? A. Because the question what is the pore size, whether it's bigger than the other, it cannot be answered. You have this distribution. You have some pores bigger than the others. You have to make the testing or you have to figure out what is the specific distribution of the various pore

14 (Pages 390 to 393)

	Page 394		Page 396
1	can get an opinion whether one is better than	1	analysis that you and Dr. Mühl devised in
2	the other.	2	Exhibit Number 20, correct?
3	Q. Okay. Have you ever analyzed	3	A. Please can you rephrase the
4	the extent to which meshes available in the	4	I didn't I'm not sure whether I got the
5	United States have an area of pore size that	5	first relationship in your sentence.
6	are larger than the Ethicon TVT® mesh, any of	6	Q. When you measure pore size,
7	them?	7	it's your expert opinion that it's
8	A. Though even the information	8	appropriate to use the effective porosity
9	about the area has some limitations, but I	9	analysis that you and Dr. Mühl devised in
10	have to say, no, I never made systemic	10	Exhibit Number 20, correct?
11	analysis of the competitor of the slings	11	A. I can say that the effective
12	from the competitors to have a systemic	12	porosity that we mirrored from the study from
13	analysis of the other devices.	13	Professor Mühl, they give some relevant,
14	Q. It's your opinion that the	14	important information about the pores, the
15	Ethicon TVT® mesh used for the treatment of	15	distribution of the pores in the Prolene®
16	stress urinary incontinence does not have	16	mesh. So, therefore, this is consistent with
17	sufficient effective porosity as measured by,	17	the histological findings and, therefore, my
18	I think it's Exhibit Number 20, the Mühl	18	opinion is based or includes this one.
19	study, to be used safely in a woman for the	19	But it wouldn't be correct to
20	treatment of stress urinary incontinence; is	20	reduce every statement about pores to the
21	that true?	21	effective porosity.
22	A. The idea was or the facts are	22	Q. But isn't it true for purposes
23	that when you look to the histology, reaction	23	of your analysis of the extent to which a
24	to this mesh material, you always hardly ever	24	mesh is designed inappropriately insofar as
	Page 395		Page 397
1	or always almost always find some bridging	1	there's adequate pore size for appropriate
2	when looking to tissue around the Prolene®	2	tissue integration that you rely on the study
3	mesh. Therefore, it behaves biologically as	3	that you and Professor Mühl prepared, Exhibit
4	a small pore meshes. Then if you and this	4	Number 20, to determine the appropriate
5	is consistent to the measurements and this is	5	porosity measurement?
6	consistent to the missing effective porosity	6	MR. ANDERSON: Objection.
7	in the Mühl testing.	7	Go ahead.
8	So this is very, very	8	THE WITNESS: It's a very long
9	consistent. If you look to the competitors,	9	sentence, but I try to answer it
10	it is hardly difficult to find just to see	10	however.
11	the differences from the images between the	11	You have to understand that the
12	various devices. So I think I assume that	12	measurement of Professor Mühl helps us
13	we will get similar results.	13	to understand and to predict the
14	MR. ANDERSON: And you were	14	tissue response.
15	pointing to page 658 of Exhibit 21	15	If you assume the textile
16	when you said "images"?	16	engineers from Ethicon would change
17	THE WITNESS: Yes. Figure 2	17	the machine a little bit and the
18	and	18	Prolene® really is a challenge for
19	QUESTIONS BY MR. THOMAS:	19	this machine. If they changed the
20	Q. Let me break down your answer a	20	machine a little bit and made the
21	little bit.	21	pores a little bit wider, then
22	When you measure pore size,	22	probably you get with the testing of
23	it's your expert opinion that it's	23	the machine an effective porosity of
24	appropriate to use the effective porosity	24	maybe 40 percent, yeah.

15 (Pages 394 to 397)

	Page 398		Page 400
1	In this case that the machine	1	Go ahead.
2	would have been changed a little bit,	2	THE WITNESS: Is it possible
3	then we would have problems because in	3	not to make a comment to this?
4	the histological analysis we saw the	4	MR. ANDERSON: No, you have to
5	scar formation, we saw this bridging	5	answer the question, but you can
6	and, therefore, it is one way it is	6	THE WITNESS: I think it is
7	one important information, the	7	inaccurate to compare textiles,
8	effective porosity, and it helps to	8	different textile constructions by the
9	explain why certain devices have some	9	use of these values for the pore size.
10	problem.	10	It is inaccurate and insufficient.
11	And we would have serious	11	QUESTIONS BY MR. THOMAS:
12	problems if there is a mesh device,	12	Q. Let me ask you this question,
13	and I don't know whether the	13	Doctor.
14	competitors have it, which may be	14	Do you know whether any mesh
15	1.1 millimeter. So that you have an	15	used for the treatment of stress urinary
16	effective porosity, then the	16	incontinence available in the United States
17	consequence for us would have to be to	17	has an effective porosity of greater than a
18	rise this limit. But in the moment,	18	thousand microns as measured by the Mühl
19	we feel consistent and satisfied with	19	study, Exhibit 20?
20	this limit.	20	A. No, I don't know.
21	QUESTIONS BY MR. THOMAS:	21	MR. THOMAS: Let's take a
22	Q. Under the Mühl study that you	22	break, please.
23	and Professor Mühl did in 2007, Exhibit	23	MR. ANDERSON: Okay.
24	Number 20, is it fair to understand that	24	(Off the record at 9:46 a.m.)
	Page 399		Page 401
1	meshes with an effective porosity with less	1	QUESTIONS BY MR. THOMAS:
2	than 1,000 microns as measured by Professor	2	Q. Doctor, did you have any
3	Mühl, you believe present an increased risk	3	involvement in the development of the 5-mil
4	of injury to patients?	4	hernia mesh used by marketed by Ethicon
5	MR. ANDERSON: Objection.	5	for pelvic strike that.
6	Go ahead.	6	Doctor, did you have any
7	THE WITNESS: Yes.	7	involvement in the development of the 5-mil
8	QUESTIONS BY MR. THOMAS:	8	hernia mesh marketed by Ethicon?
9	Q. And that meshes with an	9	A. No, I don't have.
10	effective porosity of greater than a thousand	10	Q. Do you know whether the 5-mil
11	microns strike that. Let me start over	11	hernia mesh marketed by Ethicon is still used
12	again.	12	today for the care and treatment of hernias?
13	Do you know whether any of the	13	A. No, I don't.
14	meshes on page 657 of Exhibit 21 have an	14	Q. Do you know whether the 5-mil
15	effective porosity of greater than	15	hernia mesh made by Ethicon is appropriate
16	1,000 microns as described in Exhibit 20?	16	for use in the treatment of any hernias?
17	A. No, I don't know.	17	A. For any hernias in the way that
18	Q. As you look at the relative	18	there may be some hernias that should be
19	pore sizes as measured by Moalli and others	19	can be treated with this, yes.
20	where you see that the Gynecare mesh has a	20	Q. And under what circumstances
21	pore size measured at 1379, all of the other	21	would it be appropriate to use a 5-mil
22	manufacturers mesh sizes as measured by	22	Ethicon hernia mesh?
23	Moalli are lower, correct?	23	A. If this is a in its textile
24	MR. ANDERSON: Objection.	24	properties comparable to what we know as the

16 (Pages 398 to 401)

	Page 402		Page 404
1	Prolene® mesh. If there aren't any severe	1	acceptable. Acceptable in a legal way, yes,
2	differences because I'm not familiar with	2	so all of these mesh materials that are
3	this mesh and its textile characteristics.	3	permitted to be used in surgery can be used
4	It should be considered as a heavy-weight,	4	without any legal consequences.
5	small pore, very stable mesh material and the	5	If you're thinking of the
6	indication for these mesh materials in	6	possible risks for your patients, then it has
7	general from my point it's more or less the	7	to be seen in relation to the patient and the
8	replacement of defect and not the use for the	8	specific conditions and the specific hernia
9	treatment of a hernia.	9	type whether you use a Marlex mesh, yes or
10	Q. When you say it's for the	10	not. There is no principle answer to this
11	"replacement of a defect," what do you mean?	11	question.
12	A. There are some cases where you	12	Q. Based on your training,
13	have a complex defect of all tissues. There	13	education and experience in mesh research and
14	are various layers of tissues. In a hernia,	14	your experience as a hernia surgeon, would
15	you mainly have a hole and you have some	15	you ever use Marlex mesh in any of your
16	stable surrounded tissue there and,	16	patients?
17	therefore, the principle for the treatment of	17	A. As I told you, it is the
18	a hernia is to cover the hole with a wide	18	basic question wouldn't be whether to use
19	overlap.	19	specifically Marlex or yeah, but the
20	If you don't have this strong	20	question would be whether to take a
21	tissue that can cover the mesh, then it is	21	heavy-weight, stable, small pore, whatever
22	necessary to have a more stable mesh with a	22	you want to whatever you prefer to name
23	restricted stretchability, otherwise you have	23	these type of meshes. Whether you want to
24	a bulging here. And I think still the best	24	take these more stable meshes or whether you
	Page 403		Page 405
1	indication for using these meshes are when	1	can reduce the amount of material to come to
2	you made a resection of the thoracic wall	2	a satisfying result for the patient. That is
3	here in this field and when you want to make	3	the decision you have to do, and I can
4	a repair in this area.	4	imagine that there are some conditions where
5	If you remove the ribs, then	5	Marlex is an appropriate Marlex or
6	you need some very strong material without	6	Prolene® or something like this is an
7	any significant flexibility.	7	appropriate selection.
8	Q. So would it be appropriate for	8	Q. You've described one
9	a hernia surgeon in certain indications to	9	circumstance where you thought it might be
10	use 5-mil hernia mesh for the repair of a	10	appropriate to use a 5-mil Prolene® mesh for
11	hernia defect?	11	a repair.
12	MR. ANDERSON: Objection.	12	Are there others that you can
13	Asked and answered.	13	think of?
14	Answer it again.	14	A. Maybe replacement in the brain,
15	THE WITNESS: There will be	15	but I I don't or I do not have any
16	some specific indications where you	16	specific condition in the moment where I
17	have where the surgeon can have	17	think that it is necessary to use a mesh like
18	some good arguments to use this	18	Prolene® or Marlex.
19	material, yeah.	19	Q. Over this litigation, I've
20	QUESTIONS BY MR. THOMAS:	20	heard a number of different estimates of the
21	Q. Is Marlex mesh still an	21	hernia surgeries conducted around the world
22	acceptable option for a hernia surgeon to use	22	in a year.
23	in the treatment of hernia patients?	23	What is your current best
24	A. You have to define what is	24	judgment about how many hernia surgeries are

17 (Pages 402 to 405)

	Page 406		Page 408
1	conducted around the world each year? Using	1	QUESTIONS BY MR. THOMAS:
2	mesh, I am sorry.	2	Q. Do you include any other mesh,
3	A. I never counted it, but I've	3	specific mesh brand names that are currently
4	read this publication from Sanders and	4	used when you describe the Prolene® 5-mil and
5	Kingsnorth. They estimate the use of meshes	5	the Marlex as a heavy-weight, small pore
6	with about 20 million per year. I know that	6	mesh, any other meshes on the market?
7	there are in the US about 1 million hernia	7	A. There are other manufacturers
8	operations a year. In Germany, it's about	8	as Covidien and Brown. In Germany, there
9	300,000 hernia operations in the year. I	9	are, yeah, other manufacturers as well. So
10	guess India and China will contribute	10	there are lots of finally Coda comes up
11	significantly, however, I don't know the	11	with a list of 200 different mesh materials.
12		12	MR. ANDERSON: I'm not sure he
13	figures.	13	
14	Q. Do you have any information	14	understood your question. He was
15	that allows you to estimate of the 300,000	l .	asking about how many other
16	hernia surgeries in Germany using mesh, how	15 16	manufacturers make heavy-weight, small
17	many use Prolene® 5-mil mesh?		pore meshes.
	A. For the treatment of groin	17	Did you understand that?
18	hernia, I don't know any. For the treatment	18	THE WITNESS: Well, there are
19	of incisional hernia, there will be some few	19	other yeah, there are some others
20	that are still using heavy-weight meshes.	20	from Brown, others from Covidien,
21	Q. And of the 300,000 hernias in	21	others from AraVista.
22	Germany, do you have a breakdown into groin	22	QUESTIONS BY MR. THOMAS:
23	and incisional hernias?	23	Q. Within your category that
24	A. Incisional hernia it's about	24	you've described as heavy-weight, small pore
	Page 407		Page 409
1	30,000 to 50,000. And there is a maybe	1	mesh, including as you describe it Marlex,
2	about 50, 60,000 infant hernias that are	2	the Prolene® 5-mil, do you know what
3	treated without any mesh.	3	percentage of the incisional hernia repairs
4	Q. Of the 30 to 50,000 incisional	4	use the heavy-weight, small pore meshes?
5	hernias, which is I think the only category	5	A. I don't have exact data. So
6	where you said it would be appropriate to use	6	far I have heard that market share of
7	Prolene® 5-mil hernia mesh, what percentage	7	ULTRAPRO™ was about 70 percent in Germany.
8	of those incisional hernias would be treated	8	Q. Does that mean
9	with 5-mil hernia mesh?	9	A. So that will be the most
10	MR. ANDERSON: Objection to	10	easiest way to figure out what is the
11	form. Misstates mischaracterizes	11	relationship between Prolene® and ULTRAPRO™
12	testimony.	12	in Germany.
13	Go ahead.	13	Q. Is it just as simple to say
14	THE WITNESS: I do not have	14	that the remaining 30 percent is a
15	the I do not know the market	15	heavy-weight, small pore mesh?
16	shares. I know that the predominantly	16	A. No, all of these other
17	used mesh in Germany is the ULTRAPRO <sup>TM</sup> .	17	manufacturers have light-weight, there's tie
18	It is a large pore, small pore meshes	18	mesh, light-weight, material reduced.
19	in the groin and for incisional	19	There's something midway. Again, we're
20	hernia, and I cannot remember in the	20	coming into this confusion about the weight
21	past years anyone reporting about his	21	material.
22	experience with a heavy-weight, small	22	Q. Okay.
23	pores, either Marlex or Prolene®.	23	A. The conclusion that everything
24	1 - 32,	24	else is heavy-weight is not true.
			one is nearly weight is not true.

18 (Pages 406 to 409)

	Page 410		Page 412
1	Q. Okay. That helps me.	1	Q. Is the same thing true for each
2	But what I'm trying to figure	2	of these categories that you have in heading
3	out, and maybe you don't know the answer to	3	G on page 43 of Exhibit 11, do you have any
4	this, do you have any information that leads	4	clinical data to link what you understand to
5	you to be able to estimate the percentage of	5	be these conditions being fraying, particle
6	heavy-weight, small pore meshes used for the	6	loss, machine-cut mesh, laser-cut mesh,
7	treatment of incisional hernias?	7	
		8	curling and roping, to any clinically
8	A. Apart from this estimate, no.		significant conditions?
9	Q. Okay. This estimate, I don't	9	A. No, unfortunately, I did not
10	think you gave me an estimate.	10	find any study dealing with these problems.
11	A. Estimate is 70 percent market	11	Q. Doctor, the next several pages
12	share of the ULTRAPRO <sup>TM</sup> .	12	in the description of the fraying, particle
13	Q. Okay.	13	loss section beginning on 43 of Exhibit 11,
14	A. So at least it should be	14	have you ever read any study that discusses
15	70 percent.	15	risks associated with particle loss in vivo
16	Q. Okay. Doctor, on page 43 of	16	from Ethicon mesh used for the treatment of
17	your report, which is Exhibit 11, you begin	17	stress urinary incontinence?
18	your discussion of fraying/particle	18	A. I don't know any study that is
19	loss/MCM/LCM/curling/roping.	19	testing the impact of this particle loss in
20	Do you have that?	20	an in vivo system.
21	A. I have it, yes, I see it.	21	Q. You were a hernia surgeon for
22	Q. In 2012 when your deposition	22	how long?
23	was taken, I believe your testimony at that	23	A. I have been surgeon starting in
24	time was that you didn't have any information	24	1985, and I'm still surgeon. I have been
	Page 411		Page 413
1	that fraying, particle loss from mesh insofar	1	operating hernias from 1985 to 2006.
2	as it related to pelvic organ prolapse	2	Q. Okay.
3	created any injury of clinical significance.	3	A. I'm not a hernia surgeon
4	MR. ANDERSON: Is that a	4	because in Germany you don't have hernia
5	question?	5	surgeons.
6	MR. THOMAS: Yes.	6	Q. I see.
7	MR. ANDERSON: It doesn't seem	7	Have you had any surgery
8	like one. I'll object to	8	have you done any surgeries since
9	mischaracterizing testimony.	9	December 2006?
10	QUESTIONS BY MR. THOMAS:	10	A. No. Not in humans.
11	Q. Let me start over again.	11	Q. Do you still have your license
12	As you sit here today, Doctor,	12	to practice surgery if you like?
13	are you aware of any literature that supports	13	A. Yes.
14	the contention that any fraying of TVT® mesh	14	Q. When you used mesh for the
15	leads to clinically significant results in	15	treatment of hernias, did you on occasion
16	patients who receive the mesh for the	16	have to cut the mesh?
17	treatment of stress urinary incontinence?	17	A. Usually you have to trim it,
18	A. There is good evidence that	18	yes.
19	fraying, increase of surface induces an	19	Q. And how do you trim it?
20	inferior tissue response, but I don't know	20	A. Outside of the OR field with
21	any clinical study testing the relationship	21	specific other gloves to reduce the risk for
22	between particle loss and the clinical	22	contamination there, then you get some
23	outcome, and I cannot imagine that it can be	23	sterile scissors and you're cutting out of
24	done in a clinical study.	24	the OR because when you're trimming a mesh,

19 (Pages 410 to 413)

	Page 414		Page 416
1	always you have some sort of particle loss,	1	risks. In hernia surgery if you place a mesh
2	always. There are some structures that	2	20 to 30 centimeters in a flat area and you
3	create more. It depends on the bindings, it	3	made this trimming of some corners there in
4	depends on the coarse of the filaments. So	4	relation to the abdominal, surgical trauma,
5	we know that there is some particle loss when	5	in relation to the mesh area, it is a
6	you trim this mesh and, therefore, we did it	6	considerably small area where there may be
7	outside and then we took the trimmed mesh and	7	some effect.
8	took these mesh and placed it in the groin or	8	We never selected a mesh
9	in the abdominal wall. So we try to avoid to	9	material by thinking or asking for the amount
10	trim it when it's already placed in the	10	of particle loss or, yeah, selected the mesh
11	tissues.	11	material with the least amount of particle
12	Q. And is it fair to understand	12	loss. In hernia surgery, it was not an issue
13	that for the approximately 20 million hernia	13	and I don't know anyone who is doing so.
14	surgeries conducted a year using mesh that	14	Q. Prior to this litigation, in
15	you would expect those hernia surgeries to	15	the 20 years of experience that you had in
16	involve the trimming of the mesh in some way?	16	mesh research, did you ever identify a
17	A. Yes.	17	potential risk of injury to a patient
18	Q. Do you expect based on your	18	associated with particles that are lost from
19	training, education and experience to the	19	a mesh during hernia implantation?
20	extent there was a clinical problem	20	A. Only in the sense increased
21	associated with particles being shed by mesh	21	surface generally increases the risks but not
22	in vivo during the surgery that it would be	22	specifically that we had some patient with a
23	reported in the literature now?	23	specific complication that can be related to
24	A. No. No. I don't think that	24	particle loss, no.
	Page 415		Page 417
1	the that it has that there has would	1	MR. THOMAS: I am sorry, I have
2	have to or that there should be a report	2	to take a quick break again.
3	about this and I don't think that the absence	3	MR. ANDERSON: Okay.
4	of such a report indicates that it's not a	4	(Off the record at 10:21 a.m.)
5	problem.	5	QUESTIONS BY MR. THOMAS:
6	Q. In the 20 years of mesh	6	Q. Doctor, as a part of your
7	research that you've conducted, have you ever	7	opinions in this case, have you analyzed the
8	studied the clinical effects of particle loss	8	extent to which you think that the Ethicon
9	from mesh?	9	mesh used for the treatment of stress urinary
10	A. We only studied in these years	10	incontinence sheds particles in vivo?
11	the impact of surface to bacteria adherence,	11	A. Can you please repeat the first
12	to tissue response, cellular response. So	12	word?
13	increased surface means enhancement of this	13	Q. As a part of your opinions in
14	reaction. We never made a specific	14	this case
15	investigation whether reduction of particle	15	A. Yeah.
16	loss by 10 percent leads to a change of this.	16	Q have you analyzed the extent
17	We never did it.	17	to which the Ethicon mesh used for the
18	Q. Did you ever consider analyzing	18	treatment of stress urinary incontinence
19	the extent that particles shed by hernia mesh	19	sheds particles in vivo?
20	create any risk of injury in patients?	20	A. Sorry, whether we analyze it or
21 22	A. As I told you, we are convinced	21	whether
	or we know that increase of surface will mean	22	Q. Yes.
23 24	increase of tissue response and that means	23	A. We did made a systemic
	finally increase of scar and increase of the	24	analysis, but I saw in one of the specimen

20 (Pages 414 to 417)

	Page 418		Page 420
1	that I was sent, that I got of the explants	1	A. What I expect is that you
2	there are at least one area where you can be	2	cannot divide some particle loss when you're
3	sure that this is a particle that has been	3	cutting a textile due to the way it is
4	there since the implantation.	4	manufactured. Therefore, I expect that you
5	There are a lot of other	5	will have some particle loss in both areas.
6	particles there, but you cannot be sure	6	The consequences and quantity and quantity
7	whether it's by dissecting for the	7	may be different.
8	histological preparation, but at least there	8	Q. Do you have an opinion as to in
9	is one and I made an image where this one	9	which area the particle loss is greater,
10	particle can be seen there.	10	whether it be hernia repair or stress urinary
11	Q. We'll talk about that a lot	11	incontinence?
12	later.	12	A. I think that or the particle
13	My question is I think	13	loss depends on the textile structure of a
14	you've already answered.	14	specific device, whether there are some loose
15	You've not made any systemic	15	ends that can be released from the material,
16	analysis to measure the extent to which the	16	it depends from the lengths of the cutting,
17	Ethicon mesh used in the treatment of stress	17	not from the amount of mesh material, but
18	urinary incontinence sheds particles in vivo;	18	from the lengths of the cutting, the more
19	is that fair?	19	trimming, the more particle loss you will
20	A. No quantitative analysis.	20	have. The biological consequences, they have
21	Q. Have you ever strike that.	21	to be defined in relationship to the surgical
22	Did you compare the extent to	22	trauma around.
23	which Ethicon mesh used for the treatment of	23	Q. And my question is: Do you
24	stress urinary incontinence compares to	24	have an opinion to a reasonable degree of
	Page 419		Page 421
1	hernia mesh to determine the extent to which	1	scientific or medical certainty that the
2	one sheds particles in vivo compared to the	2	hernia procedure has some degree of particle
3	other?	3	loss different from what you would expect
4	A. Compared to hernia mesh?	4	from placement of mesh for the treatment of
5	Q. Yes.	5	stress urinary incontinence?
6	A. I didn't get it.	6	A. My opinion is from what I've
7	Q. Have you made any kind of	7	seen from all of the documents that the
8	analysis to understand whether more particles	8	surgical trauma in hernia repair is much
9	are shed when you trim hernia mesh and	9	bigger than the application of a sling.
10	implant it for hernia repair as compared to	10	Q. And how does that inform your
11	the placement of Ethicon mesh for the	11	opinions about the amount of particle loss in
12	treatment of stress urinary incontinence?	12	either procedure?
13	A. First of all, it is similar	13	A. As I told you, the amount of
14	mesh. It is mainly similar textile	14	particle loss depends on the can vary
15	structures so when you cut these mesh	15	between the different devices. It depends
16	structures, I wouldn't expect that there is	16	from the lengths of the trimming away.
17	any difference. The extent of trimming	17	Q. Okay. Doctor, do you know the
18	during the gynecological or urological	18	extent to which a surgeon who implants
19	operation, I don't know.	19	Ethicon mesh, the TVT® classic, for the
20	Q. Okay. Would you expect any	20	treatment of stress urinary incontinence
21	particle loss between the placement of mesh	21	trims the mesh?
22	in the treatment of stress urinary	22	A. I'm not an expert of how to
		1 2 2	h = 1 dl = 4 de 1 = 4 de 0 D   h = 4 de 1 = 4 de 1
23 24	incontinence to be similar to the placement of mesh for the treatment of hernias?	23 24	handle this during the OR, but at least he

21 (Pages 418 to 421)

	Page 422		Page 424
1	Q. And where does he cut it?	1	tissues because we know that one place in the
2	A. He cuts it to remove the	2	tissue it is it is more difficult to
3	needles beneath the skin level.	3	remove them again. Therefore, we had the
4	Q. Does he cut it	4	similar discussions about fixation of meshes
5	intra-abdominally or outside?	5	in hernia surgery.
6	A. He tear it and cutted it and	6	Q. So when the surgeon places the
7	then it slipped back, but you have to	7	mesh underneath the urethra for the treatment
8	consider that you have a cutting of the mesh	8	of stress urinary incontinence, it's the
9	during the manufacturing process and,	9	tissue of the patient filling the pores that
10	therefore, usually you have these particles	10	keeps the mesh in place?
11	there. We all know that there are some	11	A. That is my belief, yeah.
12	during the transport, during the preparation.	12	Q. Now, do you have any
13	There are some additional particles that is	13	understanding about how the mesh used for the
14	not necessary that they are released during	14	treatment of stress urinary incontinence is
15	the trimming process, but particle loss is a	15	placed?
16	concern for textiles in general.	16	A. I've seen a video.
17	Q. For all meshes?	17	Q. Okay. And
18 19	A. Overall. The amount will	18	A. Or several videos I would say.
20	differ independent of the type of linkings and connections between the filaments.	19 20	Q. Are these were you provided
21		21	videos or did you access them on YouTube or
22	Q. When a surgeon implants Ethicon TVT® mesh for the treatment of stress urinary	22	where did you see these videos?  A. Several times on the
23	incontinence, the only cutting of the mesh	23	conferences, videos have been presented there
24	occurs after the mesh is placed, the needles	24	how to do it and there I had the opportunity
21	Page 423		Page 425
1	are pulled through the skin and then the mesh	1	to see this and I got some for this
2	is cut on the outside of the body; is that	2	litigation.
3	correct?	3	Q. From Mr. Anderson?
4	A. The trimming, yeah, outside.	4	A. Yes.
5	Q. Okay. When the mesh is	5	Q. Have you seen videotapes
6	placed strike that.	6	showing how surgeons are instructed to use
7	When a surgeon places Ethicon	7	Ethicon TVT® classic mesh for the treatment
8	mesh for the treatment of stress urinary	8	of stress urinary incontinence?
9	incontinence, after the mesh is cut as you've	9	A. Yes.
10	just described, is the mesh secured to the	10	Q. What is your understanding
11	tissue with anchors in any way, staples or	11	about how a surgeon is to place the Ethicon
12	sutures or anything of that kind?	12	mesh for the treatment of stress urinary
13	A. No. No.	13	incontinence, where and how?
14	Q. Doctor, when a surgeon places	14	MR. ANDERSON: Objection.
15	Ethicon TVT® mesh for the treatment of stress	15	Outside the scope of the opinions
16	urinary incontinence, what holds the mesh in	16	being offered in this case.
17	place?	17	THE WITNESS: I've not the
18	A. The mesh is kept in place	18	knowledge to discuss any or to give
19	because the surrounding tissue is filling or	19	comments to any details of this
20	is yeah, is filling the pores of the mesh.	20	procedure.
21 22	So if you are using a sheet without any	21 22	QUESTIONS BY MR. THOMAS:
23	pores, it will be more easy to remove this.	23	Q. Do you know how strike that.
	If you have a and this is a reason that we	∠ 3	Do you know the mechanism by
24	use textiles for the reenforcement of the	24	which the Ethicon mesh treats stress urinary

22 (Pages 422 to 425)

	Page 426		Page 428
1	incontinence?	1	work to identify the anatomy or the
2	Do you know how it works?	2	structures in the pelvic area.
3	A. I know a lot of ideas that have	3	We worked a lot of it, but I'm
4	been developed to get an understanding why	4	not prepared to give you a specific
5	this why this works and why this doesn't	5	analysis of it.
6	work sometimes. So a lot of ideas to	6	QUESTIONS BY MR. THOMAS:
7	understand this, but I don't know one way how	7	Q. Can you tell me anything about
8	it works.	8	what the mesh does to treat stress urinary
9	Q. What's your best understanding	9	incontinence?
10	as you sit here today about how Ethicon mesh	10	MR. ANDERSON: Same objections.
11	used for the treatment of stress urinary	11	THE WITNESS: Roughly we assume
12	incontinence works?	12	that with the providence of a
13	MR. ANDERSON: Same objection.	13	nonabsorbable permanent textile
14	THE WITNESS: So far I	14	structure you have a reenforcement of
15	understood that the sling provides a	15	these tissues around the midurethra,
16	relaxation of this area at certain	16	and this is a some sort of
17	strain of the patient so that you have	17	counterforce when the pelvis is going
18	this tendency to that you have	18	down. So, therefore, this is
19	these changes in the function of the	19	compensating these forces and thereby
20	bladder and the sphincters and if you	20	it improves the situation.
21	can provide a resistance there by this	21	QUESTIONS BY MR. THOMAS:
22	textile and the and the scarring	22	Q. Do you know mechanistically how
23	process around this textile.	23	mesh used for the treatment of stress urinary
24	process around any tenther	24	incontinence improves the situation as you've
	Page 427		Page 429
1	QUESTIONS BY MR. THOMAS:	1	described it?
2	Q. What role do you understand	2	A. As I told you, there are a lot
3	mesh has on the sphincter?	3	of discussions how it definitely works and I
4	MR. ANDERSON: Objection.	4	just reflect that there are controversials
5	Outside the scope of his opinions.	5	about the definite mechanism, and I cannot
6	Go ahead.	6	provide you the one mechanistic solution.
7	THE WITNESS: I know that there	7	Q. Do you have any understanding
8	are several other experts saying that	8	about whether mesh used for the treatment of
9	it is not a that it shouldn't	9	stress urinary incontinence provides support
10	impact the sphincter at all, but	10	to the urethra?
11	should be in the midurethral area, but	11	MR. ANDERSON: Same objections.
12	it is a huge field and it is not my	12	Go ahead.
13	topic to	13	THE WITNESS: Of course, it
14	QUESTIONS BY MR. THOMAS:	14	supports the tissue area there. It
15	Q. That's fine.	15	shouldn't be close to the urethra,
16	Do you have any information	16	but, of course, it supports this
17	about how the mesh relates to the bladder for	17	the urethra and this tissue as well.
18	the control of stress urinary incontinence?	18	QUESTIONS BY MR. THOMAS:
19	MR. ANDERSON: Same objection.	19	Q. You said it shouldn't be close
20	THE WITNESS: Yeah, in general,	20	to the urethra.
21	I have an impression where the sling	21	How close should it be at the
22	is, that it's not directly interfering	22	most?
23	with the wall of the bladder, but,	23	MR. ANDERSON: Same objections.
24	again, this is not the center of my	24	THE WITNESS: If it's very

23 (Pages 426 to 429)

	Page 430		Page 432
1	close, there's a high risk for	1	there has to be a distance. So I'm
2	erosion.	2	not able to recall and to replay the
3	QUESTIONS BY MR. THOMAS:	3	video and I didn't never tried to do
4	Q. Okay. So based on your	4	SO.
5	training and education and experience, how	5	QUESTIONS BY MR. THOMAS:
6	far away should a surgeon place the mesh in	6	Q. Do you have any understanding
7	order to protect against erosion?	7	about whether the mesh strike that.
8	MR. ANDERSON: Same objection.	8	Do you have any understanding
9	His experience training, education	9	about whether the Ethicon TVT® mesh used for
10	and experience, as he has told you,	10	the treatment of stress urinary incontinence
11	has nothing to do with the treatment	11	is designed to provide support for the
12	of SUI.	12	urethra?
13	THE WITNESS: I have no	13	MR. ANDERSON: Same objections.
14	experience to give you some comment on	14	He's not being offered as a
15	this. I know it is a problem for the	15	urogynecologist or a urologist.
16	surgeons doing this procedure.	16	Answer his question, if you
17	QUESTIONS BY MR. THOMAS:	17	can.
18	Q. What's a problem?	18	THE WITNESS: I only have a
19	MR. ANDERSON: Same objections.	19	very limited no, I if you
20	THE WITNESS: That in some	20	address that problem whether it's
21	patients you have a damage of the	21	designed for the use as a sling, I
22	urethra later on.	22	cannot remember very good no, I
23	QUESTIONS BY MR. THOMAS:	23	cannot remember in the documents that
24	Q. Do you know in what percentage	24	there was a specific design for this
	Page 431		Page 433
1	of patients that happens in the placement of	1	purpose that is used for the
2	mesh for stress urinary incontinence?	2	reenforcement of this area. As I told
3	MR. ANDERSON: Same objections.	3	you, yes, there is a risk of the
4	THE WITNESS: No, not I	4	damage of the urethra, yes, by the
5	don't recall. I've read it, of	5	surgeon immediately, that is one sort
6	course, but I don't recall in the	6	of damage.
7	moment.	7	The other is after two or three
8	QUESTIONS BY MR. THOMAS:	8	years you may have this damage and
9	Q. Do you know from your research	9	this is a problem with the material.
10	in this case where relative to the urethra	10	So these are has to be separated in
11	the surgeon is instructed to place the mesh?	11	this discussion that the mesh material
12	MR. ANDERSON: Same objections.	12	is specifically designed for this
13	THE WITNESS: I know this from	13	purpose. I don't get any data that
14	the video, what is said there, but	14	confirms this.
15	I've not the expertise to do this	15	QUESTIONS BY MR. THOMAS:
16	procedure or to give a comment on	16	Q. Doctor, let's go to page 28 of
17	this.	17	Exhibit 11.
18	QUESTIONS BY MR. THOMAS:	18	Page 28 of Exhibit 11 deals
19	Q. What do you recall from the	19	with that portion of your opinion that
20	video about the placement of the mesh	20	addresses mesh contraction.
21	relative to the urethra?	21	On page 29, you have a Figure 7
$\Delta \perp$	TCIALIYC IO IIIC UICHIIA!	l .	
22		22	which is a photograph of a mash avalant
22	MR. ANDERSON: Same objections.	22	which is a photograph of a mesh explant.
22 23 24		22 23 24	which is a photograph of a mesh explant.  Is that a hernia mesh explant?  A. It is a mesh that we used in

24 (Pages 430 to 433)

1 hemia   2		Page 434		Page 436
2 Q. Okay. Why? 3 A. I have to recall. It's either 4 Prolene® or it's Marlex. I guess it's 5 Marlex. I know it's written in the document, 5 but I don't recall it. 7 Q. Okay. On page 30, Figure 8, 8 again, Figure 8 is a hernia mesh? 9 A. Yes. 10 Q. And do you know what kind of 11 hemia mesh that is? 12 A. It is a composite of 12 polypropylene and the ePTFE. 13 question and the PTFE. 14 Q. And who makes that mesh? Is it 15 called a Kugel mesh? 16 A. Kugel mesh. 17 Q. And Hrisa a BARD product? 18 A. I think so, yeah. 19 Q. And Figure 9 A, that's an 19 explained Prolifi® mesh that apparently 20 you've taken from the International 21 Urogynecological Journal; is that correct? 22 A. Yes. 23 A. Yes. 24 Q. And Prolifi® mesh is a 25 different kind of mesh than what is used in 2 the treatment of stress urinary incontinence, 3 isn't it? 3 A. The placement of these mesh paperios during the OR, how it's done, how it happens during the OR, how it's done, how it's done hat's it's don't meant at the remove his so, therefore. every further finding when you try to measure something here, it will be very hard to how how the mesh is a materials three to remove this so, therefore. every further finding when you try to meas	1	hernia.	1	from this image.
A. Thave to recall. It's either  Markex. I know it's written in the document, but I don't recall it.  Q. Okay. On page 30, Figure 8, again, Figure 8 is a hernia mesh? A. Yes.  Q. And do you know what kind of hernia mesh that is? A. It is a composite of polypropylene and the ePTFE. Polypropylene and the ePTFE. A. Rigale mesh? A. Rigule mesh. A. Ithink so, yeah. A. Rigule mesh. A. Ithink so, yeah. A. Yes. C. And Figure 9 A, that's an understand the extent to which the explant may have been altered, fair? D. And Figure 9 B is a photograph of what's described in footnote into service of the semsh materials there to remove this so, therefore, every further finding when you try to measure something here, it will be very hard to impossible to get a good interpretation of the semsh materials there to remove this so, therefore, every further finding when you try to measure something here, it will be very hard to impossible to get a good interpretation of the semsh materials there to remove this so, therefore, every further finding when you try to measure something here, it will be very hard to impossible to get a good interpretation of the semsh materials there to remove this so, therefore, every further finding when you try to measure something here, it will be very hard to impossible to get a good interpretation of the semsh in andided at every step before your analysis so that you can understand that extent to which the explant may have been altered, fair?  Page 437  The WITTNESS: It depends from where it's explanted or so. So it very - it depends from where it's explanted or so. So it very - it depends from where it's expla	2		2	
4 Prolenc® or it's Marlex. I guess it's 5 Marlex. I know it's written in the document, 6 but I don't recall it. 7 Q. Okay. On page 30, Figure 8. 8 again. Figure 8 is a hernia mesh? 9 A. Yes. 9 A. Yes. 9 A. Yes. 10 Q. And do you know what kind of 11 hemia mesh that is? 12 A. It is a composite of 12 polypropylene and the ef'IFE. 13 qolypropylene and the ef'IFE. 14 Q. And who makes that mesh? Is it 15 called a Kugel mesh? 16 A. Kugel mesh. 17 Q. And that's a BARD product? 18 A. I think so, yeah. 19 Q. And Figure 9 A, that's an 19 explanted Prolift® mesh that apparently 20 vou've taken from the International 21 Urogynecological Journal; is that correct? 22 A. Yes. 23 A. Yes. 24 Q. And Prolift® mesh is a  Page 435  1 different kind of mesh than what is used in 2 the treatment of stress urinary incontinence, 3 isn't it? 4 A. Yes. 5 Q. It's called Prolene® Soft? 5 A. Yes. 6 Q. So do you have other 9 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photograph of what's described in footnote 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesk explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesk? 23 A. No. And If m convinced it is  15 the reares one specific cells at the 25 the photograph in paragraph 9 B to analyze 26 the condition of the mesk? 27 Q. Did you make any effort to use 28 the condition of the mesk? 29 A. No. And If m convinced it is  20 Q. Did you make any effort to use 21 the condition of the mesk? 22 A. No. And If m convinced it is				* *
5 Marlex. I know it's written in the document, both of the but I don't recall it.				±
6 but I don't recall it. 7 Q. Okay. On page 30, Figure 8, again, Figure 8 is a hernia mesh? 8 again, Figure 8 is a hernia mesh? 9 A. Yes. 9 A. Yes. 10 Q. And do you know what kind of 11 hernia mesh that is? 11 hernia mesh that is? 12 A. It is a composite of 12 polypropylene and the ePTPE. 13 polypropylene and the ePTPE. 14 Q. And who makes that mesh? Is it 15 called a Kugel mesh. 15 called a Kugel mesh. 16 A. Kugel mesh. 17 Q. And thar's a BARD product? 18 A. I think so, yeah. 19 Q. And Figure 9 A. thar's an 19 explanted Prolift® mesh that apparently you've taken from the International 21 Urogynecological Journal; is that correct? 21 A. Yes. 23 A. Yes. 24 Q. And Prolift® mesh is a Page 435 1 different kind of mesh than what is used in the treatment of stress urinary incontinence, 3 isn't it? 4 A. Yes. 5 Q. It's called Prolenc® Soft? 6 A. Yes. 7 Q. And page 31, Figure 9 B is a photograph of what's described in footnote 12 Lewis? 11 A. Yes. 12 Q. Did you ever observe other than by photographs of the mesh explant in addition to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the photograph of the mesh explant to is a provided to you'per understand the extent to which the explant of make appearently ago on the question out waters it will be very bard to impossible to get a good interpretation of this impossible to get a good interpretation of this.  Q. It's fair to understand that after a mesh is explanted in addition in makes kexplant that after a mesh is explanted, a person needs to know how the mesh is handled at every step before your analysis so that you can understand the extent to which the explant of makes a paragraph and the extent to which the explant in addition in the question you further on have.  16 in ti's taken,				
Q. Okay. On page 30, Figure 8, a gain, Figure 8 is a hernia mesh?   9   A. Yes.   9   9   9   9   9   9   9   9   9		•		
again, Figure 8 is a hernia mesh?  9 A. Yes. 21 A. Yes. 22 A. Yes. 23 A. Yes. 24 Q. And Prolift® mesh is a parently suit retartment of stress urinary incontinence, isn't it? 3 by hotographs of the mesh explant photos. 3 isn't it? 4 A. Yes. 5 Q. It's called Prolene® Soft? 6 A. Yes. 9 A. Yes. 10 Q. And prolift® mesh that is used in the treatment of stress urinary incontinence, isn't it? 10 A. Yes. 11 A. Yes. 12 Q. And prolift® the mesh explant photos. 13 by photographs of the mesh explant in addition to the mesh is a paragraph 9 B to analyze the photographs in paragraph 9 B to analyze the roll of Mrs. Lewis? 10 Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the resignant of the resignant in a polypropylene and the explant in addition to the mesh is analyze the condition of the mesh. 20 Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the recipilation of the mesh is analyze the recipilation of the mesh explant in addition to the mesh is analyze the polytograph of the mesh explant in addition to the mesh that was provided any other information related to the explant of fars. 21 A. No. And I'm convinced it is a fire target, it will be very hard to impossible to get a good interpretation of timese, it is most impossible to get a good interpretation of timese, it is most impossible to get a good interpretation of timese, it is fair. 22 Ut's fair to understand that after a mesh is explanted to every step before your analysis so that you can understand the extent to which the explant after a mesh is explanted to get a good interpretation of impossible to get a good interpretation of the self and after a mesh is explanted that after a mesh is explanted that af				
9 A. Yes. 10 Q. And do you know what kind of 1 hernia mesh that is? 11 hernia mesh that is? 12 A. It is a composite of 12 timpossible to get a good interpretation of this. 13 polypropylene and the ePTFE. 14 Q. And who makes that mesh? Is it 14 after a mesh is explanted, a person needs to know how the mesh is handled at every step before your analysis so that you can understand the extent to which the explant may have been altered, fair? 16 A. Rugel mesh. 17 Q. And fraire 9 A, that's an 19 Q. And Figure 9 A, that's an 19 Q. And Figure 9 A, that's an 19 Q. And Prolift® mesh that apparently you've taken from the International 21 Urogynecological Journal; is that correct? 22 If you just want to know if the treatment of stress urinary incontinence, 2 is in't it? 2 d. A. Yes. 2 Q. And Prolift® mesh than what is used in the treatment of stress urinary incontinence, 2 is in't it? 3 d. A. Yes. 4 A. Yes. 5 Q. It's called Prolene® Soft? 5 Q. It's called Prolene® Soft? 6 A. Yes. 6 Q. D. It's fair to understand that after a mesh is explanted, a person needs to know how the mesh is chandled a every step before you analysis so that you can understand the extent to which the explant may have been altered, fair?  MR. AnDERSON: Objection. Go ahead. THE WITNESS: It depends from the question you further on have. 16 if you just want to know where it's explanted or so.  So it very — it depends from where you're looking at whether this is affected by the handling of the surgeon.  Q. And page 31, Figure 9 B is a photograph of what's described in footnote 12 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than by photographs of the mesh explant in addition to the one that's in 9 B? 13 by photographs of the mesh explant in addition to the one that's in 9 B? 14 A. I do not recall. 15 A. No. And I'm convinced it is 16 A. No. And I'm convinced it is				
Q. And do you know what kind of lemain mesh that is?   11				
11 hernia mesh that is?				
A. It is a composite of  12 polypropylene and the ePTFE.  23 Q. And who makes that mesh? Is it  24 Q. And who makes that mesh? Is it  25 called a Kugel mesh.  26 A. Kugel mesh.  27 Q. And think's a BARD product?  28 A. I think so, yeah.  29 Q. And think's a BARD product?  20 explanted Proliff® mesh that apparently  20 you've taken from the International  21 Urogynecological Journal; is that correct?  22 Urogynecological Journal; is that correct?  23 A. Yes.  24 Q. And Proliff® mesh is a  Page 435  1 different kind of mesh than what is used in  2 the treatment of stress urinary incontinence,  3 isn't it?  4 A. Yes.  4 A. Yes.  5 Q. It's called Prolene® Soft?  6 A. Yes.  7 Q. And page 31, Figure 9 B is a  photograph of what's described in footnote  9 121 as the Carolyn Lewis explant photos.  10 Q. So do you have other  11 photographs of the mesh explant in addition  12 to the nee that's in 9 B?  13 polypropylene and the ePTFE.  14 A. Yes.  15 Q. Did you were observe other than  16 before your analysis so that you can  18 understand the extent to which the explant  18 may have been altered, fair?  19 MR. ANDERSON: Objection.  Go ahead.  11 HE WITNESS: It depends from  12 the question you further on have.  13 interface, it is not important to know  11 interface, it is not important to know  12 where it's explanted or so.  So it very it depends from  12 where it's explanted or so.  So it very it depends from  13 where you're looking at whether this  14 is is affected by the handling of the  15 surgeon.  16 Q. Was it important to you in your  17 where it's explanted or so.  18 that correct?  19 A. Yes.  10 Q. Did you ever observe other than  11 A. Yes.  12 Q. Did you ever observe other than  13 by photographs the actual explant of Carolyn  14 Lewis?  15 A. No.  16 Q. So do you have other  17 photographs of the mesh explant in addition  18 to the meth's in 9 B?  19 A. I do not recall.  20 Q. Did you make any effort to use  10 the treatment of the mesh?  11 A. No. And I'm convinced it is  12 the treatment of the		· ·		
13 polypropylene and the ePTFE. 14 Q. And who makes that mesh? Is it 15 called a Kugel mesh? 16 A. Kugel mesh. 17 Q. And that's a BARD product? 18 A. I think so, yeah. 19 Q. And Figure 9 A, that's an 19 Q. And Figure 9 A, that's an 19 Q. And Figure 9 A, that's an 10 explanted Prolift® mesh that apparently 11 you've taken from the International 12 Urogynecological Journal; is that correct? 13 A. Yes. 14 Q. And Prolift® mesh is a  15 Page 435 1 different kind of mesh than what is used in 15 the treatment of stress urinary incontinence, 16 A. Yes. 17 Q. And page 31, Figure 9 B is a 18 photograph of what's described in footnote 19 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 16 photographs of the mesh explant in addition to the one that's in 9 B? 18 A. No. And I'm convinced it is 19 Q. Did you make any effort to use 10 Le wis? 10 Did you make any effort to use 11 the proposition of the mesh? 12 the photograph in paragraph 9 B to analyze 12 the condition of the mesh? 13 A. No. And I'm convinced it is 10 A. No. And I'm convinced it is 11 A. No. And I'm convinced it is 12 the freatment of the explant after a mesh is explanted, a person needs to know how themesh is handled at every step before your analysis so that you can understand the extent to which the explant may have been altered, fair? 17 MR. ANDERSON: Objection. 19 Go ahead. 11 THE WITNESS: It depends from the question you further on have. 11 interface, it is not important to know where it's explanted or so. 12 is int it? 13 isn't it? 14 interface, it is not important to know where it's explanted or so. 15 isn't it? 16 A. Yes. 17 Q. And page 31, Figure 9 B is a photograph of what's described in footnote 19 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs of the mesh explant in addition to the one that's in 9 B? 18 A. No. 19 A				
14 Q. And who makes that mesh? Is it called a Kugel mesh. 16 A. Kugel mesh. 17 Q. And that's a BARD product? 18 A. I think so, yeah. 19 Q. And figure 9 A, that's an 19 explanted Prolift® mesh that apparently you've taken from the International 21 Urogynecological Journal; is that correct? 23 A. Yes. 24 Q. And Prolift® mesh than what is used in 2 the treatment of stress urinary incontinence, 3 isn't it? 4 A. Yes. 5 Q. It's called Prolene® Soft? 6 A. Yes. Q. And apage 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. 18 photographs of what's described in footnote 121 as the Carolyn Lewis? 19 Q. So do you have other photographs of the mesh explant in addition to the one that's in 9 B? 10 Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the condition of the mesh? 20 Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the condition of the mesh? 21 A. No. And I'm convinced it is affect a mesh is sandled at every step before your analysis so that you can understand the extent to which the explant may have been altered, fair?  17 may have been altered, fair?  18 may have been altered, fair?  19 MR. ANDERSON: Objection.  Go ahead.  17 THE WITNESS: It depends from the question you further on have.  21 if you just want to know if there are some specific cells at the  Page 437  1 interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  Q. Yes.  A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there.  Q. Other than the image that's on page 31 of your report and the histological cut that gives you are restri		A. It is a composite of	12	this.
15 called a Kugel mesh?  A. Kugel mesh.  A. Kugel mesh.  A. I think so, yeah.  19 Q. And frigure 9 A, that's an  20 explanted Prolift® mesh that apparently 21 you've taken from the International 22 Urogynecological Journal; is that correct? 23 A. Yes.  4 Q. And Prolift® mesh is a  24 page 435  1 different kind of mesh than what is used in the treatment of stress urinary incontinence, 3 isn't it?  4 A. Yes.  5 Q. It's called Prolene® Soft? 4 A. Yes.  6 Q. And page 31, Figure 9 B is a photograph of what's described in footnote 12 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than by photographs of the mesh explant in addition to the one that's in 9 B? 18 A. No. 20 Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the condition of the mesh? 21 Called Prolene in Figure 12 Called Prolene in Page 435  22 know how the mesh is handled at every step before your analysis so that you can bunders tand the extent to which the explant in addition to the one that's in 9 B? 20 And page 31, Figure 9 B is a photographs of the mesh explant in addition to to the one that's in 9 B? 21 A. No. And I'm convinced it is 22 know how the mesh is handled at every step before your analysis so that you can bunders that was that the explant of the exp	13	polypropylene and the ePTFE.	13	Q. It's fair to understand that
16 A. Kugel mesh. 17 Q. And that's a BARD product? 18 A. I think so, yeah. 19 Q. And Figure 9 A, that's an 20 explanted Prolift® mesh that apparently 21 you've taken from the International 22 Urogynecological Journal; is that correct? 23 A. Yes. 24 Q. And Prolift® mesh is a  Page 435  1 different kind of mesh than what is used in 2 the treatment of stress urinary incontinence, 3 isn't it? 4 A. Yes. 5 Q. It's called Prolene® Soft? 6 A. Yes. 7 Q. And page 31, Figure 9 B is a 8 photograph of what's described in footnote 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 15 by photographs the actual explant of Carolyn 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 12 the read and you an understand the extent to which the explant and the wave been altered, fair?  19 MR. ANDERSON: Objection. 20 ahead. 21 THE WITNESS: It depends from the question you further on have. 21 If you just want to know if 22 there are some specific cells at the 23 interface, it is not important to know where it's explanted or so. 3 So it very — it depends from 4 where it's explanted or so. 3 So it very — it depends from 4 where it's explanted or so. 3 So it very — it depends from 4 where it's explanted or so. 4 Wesre it's explanted or so. 4 Were it's explanted or so. 4 Were it's explanted or so. 4 Were it's explanted or so. 5 So it very — it depends from 4 where it's explanted or so. 4 Were it's explanted or so. 5 Out very — it depe	14	Q. And who makes that mesh? Is it	14	after a mesh is explanted, a person needs to
16 A. Kugel mesh. 17 Q. And that's a BARD product? 18 A. I think so, yeah. 19 Q. And Figure 9 A, that's an 20 explanted Prolift® mesh that apparently 21 you've taken from the International 22 Urogynecological Journal; is that correct? 23 A. Yes. 24 Q. And Prolift® mesh is a  Page 435  1 different kind of mesh than what is used in 2 the treatment of stress urinary incontinence, 3 isn't it? 4 A. Yes. 5 Q. It's called Prolene® Soft? 6 A. Yes. 7 Q. And page 31, Figure 9 B is a 8 photograph of what's described in footnote 10 Is that correct? 11 A. Yes. 10 Q. Did you ever observe other than 11 by photographs the actual explant of Carolyn 12 Lewis? 13 A. No. 14 C. O. So do you have other 15 photographs of the mesh explant in addition 16 to the one that's in 9 B? 17 Q. Did you make any effort to use 18 the read and you can understand the extent to which the explant and the wave been altered, fair?  19 MR. ANDERSON: Objection. 20 Go ahead. 21 THE WITNESS: It depends from the therenational the valuation and the extent to which the explant of may have been altered, fair?  19 MR. ANDERSON: Objection. 20 THE WITNESS: It depends from the question you further on have. 21 If you just want to know if the question you further on have. 22 If you just want to know if the question you further on have. 23 If you just want to know if the reasons especific cells at the 24 there are some specific cells at the 25 Ware it's explanted or so. 26 So it very — it depends from where it's explanted or so. 36 So it very — it depends from where it's explanted or so. 37 So it very — it depends from the tereatment of stress urinary incontinence, 38 So it very — it depends from the tereatment of sures same specific cells at the where it's explanted or so. 39 So it very —	15	called a Kugel mesh?	15	know how the mesh is handled at every step
17 Q. And that's a BARD product? 18 A. I think so, yeah. 19 Q. And Figure 9 A, that's an 20 explanted Prolift® mesh that apparently 21 you've taken from the International 22 Urogynecological Journal; is that correct? 23 A. Yes. 24 Q. And Prolift® mesh is a  Page 435  1 different kind of mesh than what is used in 2 the treatment of stress urinary incontinence, 3 isn't it? 4 A. Yes. 5 Q. It's called Prolene® Soft? 6 A. Yes. 7 Q. And page 31, Figure 9 B is a 8 photograph of what's described in footnote 9 121 as the Carolyn Lewis explant photos. 10 Lewis? 11 A. No. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photograph of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 12 the fine xtent to which the explant may have been altered, fair? 19 MR. ANDERSON: Objection. 20 Go ahead. 21 THE WITNESS: It depends from 22 the question you further on have. 23 If you just want to know if 24 there are some specific cells at the 24 page 437  Page 437  1 different kind of mesh than what is used in 2 interface, it is not important to know where it's explanted or so. 3 So it very — it depends from 2 where it's explanted or so. 3 So it very — it depends from 3 Where you're looking at whether this is affected by the handling of the 3 wiere you're looking at whether this is affected by the handling of the 3 wiere you're looking at whether this is affected by the handling of the 3 were you're looking at whether this is affected by the handling of the 3 where you're looking at whether this is affected by the handling of the 3 were you're looking at whether this is affected by the handling of the 4 A. Yes. 4 Q. Was it important to you in your 4 work in this case that the mesh that was 4 provided to you for analysis had been cut 5 provided to you for analysis had been cut 6 provided to you for analysis had been cut 7 provided to you for analysis had been cut 8 provided to you for a	16	_	16	
18 A. I think so, yeah. 19 Q. And Figure 9 A, that's an 20 explanted Prolift® mesh that apparently 21 you've taken from the International 22 Urogynecological Journal; is that correct? 23 A. Yes. 24 Q. And Prolift® mesh is a  Page 435  1 different kind of mesh than what is used in 2 the treatment of stress urinary incontinence, 3 isn't it? 4 A. Yes. 4 Q. It's called Prolene® Soft? 5 Q. It's called Prolene® Soft? 6 A. Yes. 7 Q. And page 31, Figure 9 B is a 8 photograph of what's described in footnote 9 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 Q. So do you have other 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 20 A. No. And I'm convinced it is 21 may have been altered, fair? 22 MR. ANDERSON: Objection. 23 Go ahead. 24 the UTINESS: It depends from 25 the question you further on have. 26 I'you just want to know if 26 there are some specific cells at the 27 et ale with the reas some specific cells at the 28 Page 437 29 there are some specific cells at the 29 a there are some specific cells at the 20 a li tyou just want to know if 21 there are some specific cells at the 21 interface, it is not important to know 22 where it's explanted or so. 23 So it very — it depends from 24 where it's explanted or so. 25 So it very — it depends from 26 where it's explanted or so. 27 So it very — it depends from 27 where you're looking at whether this is affected by the handling of the 28 surgeon. 29 QUESTIONS BY MR. THOMAS: 30 QUESTIONS BY MR. THOMAS: 40 A. Yes. 41 prior to being sent to you? 41 A. The fact that I was provided 41 only the histological cut that gives some 42 limitations to the analysis, of course. So 43 you are restricted to what you see there. 44 A. No. And I'm convinced it is 45 A. No. And I'm convinced it is 46 A. Yes. 47 Q. Other than the image that's on 47 page 37		•		
19				
20 explanted Prolift® mesh that apparently 21 you've taken from the International 22 Urogynecological Journal; is that correct? 23 A. Yes. 24 Q. And Prolift® mesh is a  Page 435  1 different kind of mesh than what is used in 25 the treatment of stress urinary incontinence, 3 isn't it? 4 A. Yes. 5 Q. It's called Prolene® Soft? 6 A. Yes. 7 Q. And page 31, Figure 9 B is a 8 photograph of what's described in footnote 9 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to photograph of the mesh explant in paragraph 9 B to analyze 19 Le word in page 31 of your report and the histological cuts that you've just described, were you provided to you for analysis, of course. So 18 you are restricted to what you see there. 19 A. I do not recall. 20 Go ahead. THE WITNESS: It depends from the question you further on have. 12 the question you further on have. 14 the question you further on have. 15 In the question you further on have. 16 the question you further on have. 17 play in the plotograph of the mesh explant in addition to the one that's in 9 B? 28				
21 you've taken from the International 22 Urogynecological Journal; is that correct? 23 A. Yes. 24 Q. And Prolift® mesh is a  Page 435  1 different kind of mesh than what is used in 2 the treatment of stress urinary incontinence, 3 isn't it?  4 A. Yes.  9 Lit's called Prolene® Soft?  6 A. Yes.  7 Q. And page 31, Figure 9 B is a 8 photograph of what's described in footnote 9 121 as the Carolyn Lewis explant photos. 10 Lewis? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 20 Lit's called rorect? 21 A. No. And I'm convinced it is 21 THE WITNESS: It depends from the question you further on have. 22 If you just want to know if there are some specific cells at the 24 there are some specific cells at the 25 Page 437  Page 437  1 different kind of mesh than what is used in 1 interface, it is not important to know where it's explanted or so. 2 So it very it depends from where it's explanted or so. 3 isn't it? 3 So it very it depends from where it's explanted or so. 4 Cut insection you import and very in your for surgeon. 4 Q. Was it important to you in your work in this case that the mesh that was provided you for analysis had been cut prior to being sent to you? 4 A. Cut in sections, in 4 A. Cut in sections, in 5 A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there. 4 Q. Other than the image that's on page 31 of your report and the histological cut that you've just described, were you provided any other information related to the explant of Mrs. Lewis?  21 cut shat you've just described, were you provided any other information related to the explant of Mrs. Lewis?				
Urogynecological Journal; is that correct?  A. Yes.  Q. And Prolift® mesh is a  Page 435    different kind of mesh than what is used in 2 the treatment of stress urinary incontinence, 3 isn't it?   different kind of mesh than what is used in 2 the treatment of stress urinary incontinence, 3 isn't it?   different kind of mesh than what is used in 2 the treatment of stress urinary incontinence, 3 isn't it?   different kind of mesh than what is used in 2 the treatment of stress urinary incontinence, 2 the page 437    different kind of mesh than what is used in the reatment of stress urinary incontinence, 2 the page 437    different kind of mesh than what is used in the page 437    different kind of mesh than unit of stress urinary incontinence, 2 the page 437    different kind of mesh than what is used in interface, it is not important to know where it's explanted or so. So it very it depends from where it's explanted or so. So it very it depends from where it's explanted or so. So it very it depends from where it's explanted or so. So it very it depends from where it's explanted or so. So it very it depends from where it's explanted or so. So it very				
A. Yes.  Q. And Prolift® mesh is a  Page 435  different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes.  Q. It's called Prolene® Soft?  A. Yes.  Q. And page 31, Figure 9 B is a photograph of what's described in footnote Iss that correct?  A. Yes.  Q. Did you ever observe other than by photographs of the mesh explant in addition to the one that's in 9 B?  A. I do not recall.  Q. Did you make any effort to use the condition of the mesh?  A. No. And I'm convinced it is  Page 437  If you just want to know if there are some specific cells at the  Page 437  If you just want to know if there are some specific cells at the  Page 437  In interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological cut that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there.  Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the condition of the mesh?  A. No. And I'm convinced it is				
24  Q. And Prolift® mesh is a  Page 435  different kind of mesh than what is used in the treatment of stress urinary incontinence, isin't it?  A. Yes.  Q. It's called Prolene® Soft? A. Yes.  Q. And page 31, Figure 9 B is a photograph of what's described in footnote 11 A. Yes.  Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis?  A. No. Q. So do you have other photographs of the mesh explant in addition the photograph of by no and paragraph 9 B to analyze the condition of the mesh? A. No. And I'm convinced it is  Page 437  there are some specific cells at the page 437  there are some specific cells at the page 437  there are some specific cells at the page 437  there are some specific cells at the page 437  there are some specific cells at the page 437  there are some specific cells at the page 437  there are some specific cells at the page 437  there are some specific cells at the page 437  there are some specific cells at the page 437  there are some specific cells at the page 437  there are some specific cells at the there are some specific cells at the page 437  there are some specific cells at the page 437  there are some specific cells at the mesh explant to know where it's explanted or so. So it very it depends from where voi're looking at whether this is affected by the handling of the surgeon.  Q. Was it important to you in your work in this case th		• •		
different kind of mesh than what is used in the treatment of stress urinary incontinence, isin't it?  A. Yes.  Q. It's called Prolene® Soft? A. Yes.  Q. And page 31, Figure 9 B is a photograph of what's described in footnote Is that correct?  A. Yes.  Q. Didyou ever observe other than by photographs of the mesh explant in addition photographs of the mesh explant in addition to the one that's in 9 B?  A. I do not recall.  Q. Did you make any effort to use the condition of the mesh?  A. No. And I'm convinced it is  different kind of mesh than what is used in interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there.  Q. Other than the image that's on page 31 of your report and the histological cuts that you're just described, were you provided any other information related to the explant of Mrs. Lewis?				
different kind of mesh than what is used in the treatment of stress urinary incontinence, sin't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote Is that correct? A. Yes. Q. Did you ever observe other than Q. Did you sever observe other than Q. So do you have other photographs of the mesh explant in addition to the one that's in 9 B? A. I do not recall. Q. Did you make any effort to use the condition of the mesh? A. No. And I'm convinced it is  1 interface, it is not important to know where it's explanted or so. So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  Q. Was it important to you where it's explanted or so. So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  Q. Was it important to know  where it's explanted or so.  3 So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you? A. Cut in sections, in histological sections?  4 Q. Yes.  A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there. Q. Other than the image that's on page 31 of your report and the histological cuts that you've just described, were you provided any other information related to the explant of Mrs. Lewis?	24	Q. And Prolift® mesh is a	24	there are some specific cells at the
the treatment of stress urinary incontinence,     isn't it?  A. Yes.  Q. It's called Prolene® Soft?  A. Yes.  Q. And page 31, Figure 9 B is a  photograph of what's described in footnote  Is that correct?  A. Yes.  Q. Did you ever observe other than  by photographs the actual explant of Carolyn  Lewis?  A. No.  Q. So do you have other  photographs of the mesh explant in addition  to the one that's in 9 B?  A. I do not recall.  Q. Did you make any effort to use  A. No. And I'm convinced it is  where it's explanted or so.  So it very it depends from  where you're looking at whether this  is affected by the handling of the  surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your  work in this case that the mesh that was  provided to you for analysis had been cut  prior to being sent to you?  A. Cut in sections, in  histological sections?  4 Q. Yes.  A. The fact that I was provided  only the histological cut that gives some  limitations to the analysis, of course. So  you are restricted to what you see there.  Q. Did you make any effort to use  the photograph in paragraph 9 B to analyze  the condition of the mesh?  A. No. And I'm convinced it is		Dago 435		
3 isn't it? 4 A. Yes. 5 Q. It's called Prolene® Soft? 6 A. Yes. 7 Q. And page 31, Figure 9 B is a 8 photograph of what's described in footnote 9 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 23 A. No. And I'm convinced it is  3 So it very it depends from where where ry is affected by the handling of the where you're looking at whether this is affected by the handling of the where you're looking at whether this is affected by the handling of the where you're looking at whether this is affected by the handling of the surgeon.  7 QUESTIONS BY MR. THOMAS:  8 Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  14 Q. Yes.  15 A. The fact that I was provided only the histological cut that gives some 16 only the histological cut that gives some 17 limitations to the analysis, of course. So 18 you are restricted to what you see there. 19 Q. Other than the image that's on 19 page 31 of your report and the histological cuts that you've just described, were you provided any other information related to the explant of Mrs. Lewis?		rage 433		Page 437
3 isn't it? 4 A. Yes. 5 Q. It's called Prolene® Soft? 6 A. Yes. 7 Q. And page 31, Figure 9 B is a 8 photograph of what's described in footnote 9 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 23 A. No. And I'm convinced it is  3 So it very it depends from where eyou're looking at whether this is affected by the handling of the where you're looking at whether this is affected by the handling of the where you're looking at whether this is affected by the handling of the where you're looking at whether this is affected by the handling of the surgeon.  4 QUESTIONS BY MR. THOMAS:  8 Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in 13 histological sections?  14 Q. Yes.  A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there.  9 Q. Other than the image that's on page 31 of your report and the histological cuts that you've just described, were you provided any other information related to the explant of Mrs. Lewis?	1		1	
4 A. Yes. 5 Q. It's called Prolene® Soft? 6 A. Yes. 7 Q. And page 31, Figure 9 B is a 8 photograph of what's described in footnote 9 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 23 A. No. And I'm convinced it is  4 where you're looking at whether this is affected by the handling of the surgeon. 7 QUESTIONS BY MR. THOMAS: 8 Q. Was it important to you in your 9 work in this case that the mesh that was 9 provided to you for analysis had been cut 11 prior to being sent to you? 12 A. Cut in sections, in 13 histological sections? 14 Q. Yes. 15 A. The fact that I was provided 16 only the histological cut that gives some 17 limitations to the analysis, of course. So 18 you are restricted to what you see there. 19 Q. Other than the image that's on 19 age 31 of your report and the histological 20 cuts that you've just described, were you 21 provided any other information related to the 23 explant of Mrs. Lewis?		different kind of mesh than what is used in		interface, it is not important to know
5 Q. It's called Prolene® Soft? 6 A. Yes. 7 Q. And page 31, Figure 9 B is a 8 photograph of what's described in footnote 9 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 23 A. No. And I'm convinced it is 20 It's called Prolene® Soft? 6 A. Yes. 6 surgeon. 7 QUESTIONS BY MR. THOMAS: 8 Q. Was it important to you in your 9 work in this case that the mesh that was 9 provided to you for analysis had been cut 10 prior to being sent to you? 12 A. Cut in sections, in 13 histological sections? 14 Q. Yes. 15 A. The fact that I was provided 16 only the histological cut that gives some 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 Q. Other than the image that's on 20 Q. Did you make any effort to use 21 cuts that you've just described, were you 22 the condition of the mesh? 23 A. No. And I'm convinced it is	2	different kind of mesh than what is used in the treatment of stress urinary incontinence,	2	interface, it is not important to know where it's explanted or so.
6 A. Yes. 7 Q. And page 31, Figure 9 B is a 8 photograph of what's described in footnote 9 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 23 A. No. And I'm convinced it is  6 surgeon. 7 QUESTIONS BY MR. THOMAS: 8 Q. Was it important to you in your 9 work in this case that the mesh that was 10 provided to you for analysis had been cut 11 prior to being sent to you? 12 A. Cut in sections, in 13 histological sections? 14 Q. Yes. 15 A. The fact that I was provided 16 only the histological cut that gives some 17 limitations to the analysis, of course. So 18 you are restricted to what you see there. 19 Q. Other than the image that's on 20 page 31 of your report and the histological 21 cuts that you've just described, were you 22 provided any other information related to the 23 explant of Mrs. Lewis?	2 3	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?	2 3	interface, it is not important to know where it's explanted or so.  So it very it depends from
7 Q. And page 31, Figure 9 B is a 8 photograph of what's described in footnote 9 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 23 A. No. And I'm convinced it is  7 QUESTIONS BY MR. THOMAS:  8 Q. Was it important to you in your 9 work in this case that the mesh that was 10 provided to you for analysis had been cut 11 prior to being sent to you? 12 A. Cut in sections, in 13 histological sections? 14 Q. Yes. 15 A. The fact that I was provided 16 only the histological cut that gives some 17 limitations to the analysis, of course. So 18 you are restricted to what you see there. 19 Q. Other than the image that's on 20 page 31 of your report and the histological 21 cuts that you've just described, were you 22 provided any other information related to the 23 explant of Mrs. Lewis?	2 3 4	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes.	2 3 4	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this
8 photograph of what's described in footnote 9 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 23 A. No. And I'm convinced it is  8 Q. Was it important to you in your 9 work in this case that the mesh that was 10 provided to you for analysis had been cut 11 prior to being sent to you? 12 A. Cut in sections, in 13 histological sections? 14 Q. Yes. 15 A. The fact that I was provided 16 only the histological cut that gives some 17 limitations to the analysis, of course. So 18 you are restricted to what you see there. 19 Q. Other than the image that's on 20 page 31 of your report and the histological 21 cuts that you've just described, were you 22 provided any other information related to the 23 explant of Mrs. Lewis?	2 3 4 5	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft?	2 3 4 5	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the
9 121 as the Carolyn Lewis explant photos. 10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 21 work in this case that the mesh that was 10 provided to you for analysis had been cut 11 prior to being sent to you? 12 A. Cut in sections, in 13 histological sections? 14 Q. Yes. 15 A. The fact that I was provided 16 only the histological cut that gives some 17 limitations to the analysis, of course. So 18 you are restricted to what you see there. 19 Q. Other than the image that's on 20 page 31 of your report and the histological 21 cuts that you've just described, were you 22 provided any other information related to the 23 A. No. And I'm convinced it is 24 cuts that you've just described of the explant of Mrs. Lewis?	2 3 4 5 6	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes.	2 3 4 5 6	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.
10 Is that correct? 11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 23 A. No. And I'm convinced it is  10 provided to you for analysis had been cut 11 prior to being sent to you? 12 A. Cut in sections, in 13 histological sections? 14 Q. Yes. 15 A. The fact that I was provided 16 only the histological cut that gives some 17 limitations to the analysis, of course. So 18 you are restricted to what you see there. 19 Q. Other than the image that's on 20 page 31 of your report and the histological 21 cuts that you've just described, were you 22 provided any other information related to the 23 explant of Mrs. Lewis?	2 3 4 5 6 7	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a	2 3 4 5 6 7	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:
11 A. Yes. 12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 21 Did you make any effort to use 23 A. No. And I'm convinced it is 21 Drior to being sent to you? 24 A. Cut in sections, in 25 A. Cut in sections, in 26 A. Cut in sections, in 26 A. Cut in sections? 26 A. Cut in sections? 27 A. Cut in sections? 28 A. Cut in sections, in 29 A. Cut in sections? 20 A. Cut in sections? 21 histological sections? 21 Ib prior to being sent to you? 20 A. Cut in sections, in 20 A. The fact that I was provided 20 only the histological cut that gives some 27 limitations to the analysis, of course. So 28 you are restricted to what you see there. 29 page 31 of your report and the histological 20 cuts that you've just described, were you 21 provided any other information related to the 22 explant of Mrs. Lewis?	2 3 4 5 6 7 8	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote	2 3 4 5 6 7 8	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your
12 Q. Did you ever observe other than 13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 23 A. No. And I'm convinced it is  12 A. Cut in sections, in 13 histological sections? 14 Q. Yes. 15 A. The fact that I was provided 16 only the histological cut that gives some 17 limitations to the analysis, of course. So 18 you are restricted to what you see there. 19 Q. Other than the image that's on 20 page 31 of your report and the histological 21 cuts that you've just described, were you 22 provided any other information related to the 23 explant of Mrs. Lewis?	2 3 4 5 6 7 8 9	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos.	2 3 4 5 6 7 8	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was
13 by photographs the actual explant of Carolyn 14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 23 A. No. And I'm convinced it is  13 histological sections? 14 Q. Yes. 15 A. The fact that I was provided 16 only the histological cut that gives some 17 limitations to the analysis, of course. So 18 you are restricted to what you see there. 19 Q. Other than the image that's on 20 page 31 of your report and the histological 21 cuts that you've just described, were you 22 provided any other information related to the 23 explant of Mrs. Lewis?	2 3 4 5 6 7 8 9	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. Is that correct?	2 3 4 5 6 7 8 9	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut
14 Lewis? 15 A. No. 16 Q. So do you have other 17 photographs of the mesh explant in addition 18 to the one that's in 9 B? 19 A. I do not recall. 20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 23 A. No. And I'm convinced it is 24 Q. Yes. 25 A. The fact that I was provided 26 only the histological cut that gives some 27 limitations to the analysis, of course. So 28 you are restricted to what you see there. 29 page 31 of your report and the histological 21 cuts that you've just described, were you 22 provided any other information related to the 23 explant of Mrs. Lewis?	2 3 4 5 6 7 8 9 10	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. Is that correct? A. Yes.	2 3 4 5 6 7 8 9 10	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?
A. No.  Q. So do you have other  photographs of the mesh explant in addition  to the one that's in 9 B?  A. I do not recall.  Q. Did you make any effort to use  the photograph in paragraph 9 B to analyze  the condition of the mesh?  A. No. And I'm convinced it is  A. The fact that I was provided  only the histological cut that gives some  limitations to the analysis, of course. So  18 you are restricted to what you see there.  Q. Other than the image that's on  page 31 of your report and the histological  cuts that you've just described, were you  provided any other information related to the  explant of Mrs. Lewis?	2 3 4 5 6 7 8 9 10 11	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos.  Is that correct? A. Yes. Q. Did you ever observe other than	2 3 4 5 6 7 8 9 10 11 12	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in
Q. So do you have other photographs of the mesh explant in addition to the one that's in 9 B?  A. I do not recall. Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the condition of the mesh? A. No. And I'm convinced it is  16 only the histological cut that gives some 17 limitations to the analysis, of course. So 18 you are restricted to what you see there. 19 Q. Other than the image that's on 20 page 31 of your report and the histological 21 cuts that you've just described, were you 22 provided any other information related to the 23 explant of Mrs. Lewis?	2 3 4 5 6 7 8 9 10 11 12 13	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. Is that correct? A. Yes. Q. Did you ever observe other than by photographs the actual explant of Carolyn	2 3 4 5 6 7 8 9 10 11 12 13	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?
photographs of the mesh explant in addition to the one that's in 9 B?  A. I do not recall.  Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the condition of the mesh?  A. No. And I'm convinced it is  17 limitations to the analysis, of course. So you are restricted to what you see there.  Q. Other than the image that's on page 31 of your report and the histological cuts that you've just described, were you provided any other information related to the explant of Mrs. Lewis?	2 3 4 5 6 7 8 9 10 11 12 13 14	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos.  Is that correct? A. Yes. Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis?	2 3 4 5 6 7 8 9 10 11 12 13 14	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  Q. Yes.
18 to the one that's in 9 B?  19 A. I do not recall.  20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh?  23 A. No. And I'm convinced it is  18 you are restricted to what you see there.  19 Q. Other than the image that's on 20 page 31 of your report and the histological 21 cuts that you've just described, were you 22 provided any other information related to the 23 explant of Mrs. Lewis?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. Is that correct? A. Yes. Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis? A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  Q. Yes.  A. The fact that I was provided
A. I do not recall.  Q. Did you make any effort to use  19 Q. Other than the image that's on  20 page 31 of your report and the histological  21 the photograph in paragraph 9 B to analyze  22 the condition of the mesh?  23 A. No. And I'm convinced it is  19 Q. Other than the image that's on  20 page 31 of your report and the histological  21 cuts that you've just described, were you  22 provided any other information related to the  23 explant of Mrs. Lewis?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. Is that correct? A. Yes. Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis? A. No. Q. So do you have other	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  Q. Yes.  A. The fact that I was provided only the histological cut that gives some
Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the condition of the mesh?  A. No. And I'm convinced it is  page 31 of your report and the histological cuts that you've just described, were you provided any other information related to the explant of Mrs. Lewis?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. Is that correct? A. Yes. Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis? A. No. Q. So do you have other photographs of the mesh explant in addition	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  Q. Yes.  A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So
20 Q. Did you make any effort to use 21 the photograph in paragraph 9 B to analyze 22 the condition of the mesh? 23 A. No. And I'm convinced it is 20 page 31 of your report and the histological 21 cuts that you've just described, were you 22 provided any other information related to the 23 explant of Mrs. Lewis?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. Is that correct? A. Yes. Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis? A. No. Q. So do you have other photographs of the mesh explant in addition	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  Q. Yes.  A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So
the photograph in paragraph 9 B to analyze the condition of the mesh?  A. No. And I'm convinced it is  21 cuts that you've just described, were you provided any other information related to the explant of Mrs. Lewis?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. Is that correct? A. Yes. Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis? A. No. Q. So do you have other photographs of the mesh explant in addition to the one that's in 9 B?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  Q. Yes.  A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there.
the condition of the mesh?  2 provided any other information related to the 2 provided any other information related to the 2 explant of Mrs. Lewis?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. Is that correct? A. Yes. Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis? A. No. Q. So do you have other photographs of the mesh explant in addition to the one that's in 9 B? A. I do not recall.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  Q. Yes.  A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there.  Q. Other than the image that's on
23 A. No. And I'm convinced it is 23 explant of Mrs. Lewis?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. Is that correct? A. Yes. Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis? A. No. Q. So do you have other photographs of the mesh explant in addition to the one that's in 9 B? A. I do not recall. Q. Did you make any effort to use	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  Q. Yes.  A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there.  Q. Other than the image that's on page 31 of your report and the histological
	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. Is that correct? A. Yes. Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis? A. No. Q. So do you have other photographs of the mesh explant in addition to the one that's in 9 B? A. I do not recall. Q. Did you make any effort to use the photograph in paragraph 9 B to analyze	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  Q. Yes.  A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there.  Q. Other than the image that's on page 31 of your report and the histological cuts that you've just described, were you
	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?  A. Yes. Q. It's called Prolene® Soft? A. Yes. Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos. Is that correct? A. Yes. Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis? A. No. Q. So do you have other photographs of the mesh explant in addition to the one that's in 9 B? A. I do not recall. Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the condition of the mesh?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	interface, it is not important to know where it's explanted or so.  So it very it depends from where you're looking at whether this is affected by the handling of the surgeon.  QUESTIONS BY MR. THOMAS:  Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?  A. Cut in sections, in histological sections?  Q. Yes.  A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there.  Q. Other than the image that's on page 31 of your report and the histological cuts that you've just described, were you provided any other information related to the

25 (Pages 434 to 437)

	Page 438		Page 4	440
1	operation by the surgeon.	1	therefore, yeah, you have a high risk for	
2	Q. Okay.	2	shrinkage and contraction. We know to say	
3	A. And the pathology statement	3	it already here, we know that there are some	
4	from the hospital. So some medical records.	4	patients where it's less and there are other	
5	Q. Other than the operating room	5	patients where it's more pronounced.	
6	report and the pathology report from the	6	But what we have learned in	
7	hospital after the explant, do you recall	7	these 20 years is that Prolene®, with its	
8	receiving any other information about Carolyn	8	structure, with its weight, with its amount	
9	Lewis?	9	of material, it's a high risk for	
10	A. Yeah, I recall 10, 11 files	10	contraction.	
11	with medical records to various extents and	11	QUESTIONS BY MR. THOMAS:	
12	thousands of pages with lab results and	12	Q. In your 20 years of research,	
13	post-analysis and	13	have you specifically studied the extent to	
14	Q. Okay. Did you understand that	14	which Ethicon Prolene® mesh used in the	
15	you received, to the extent that it was	15	treatment of stress urinary incontinence	
16	available, her medical history?	16	contracts in vivo in the stress urinary	
17	A. Yes.	17	incontinence application specifically?	
18	Q. Okay. So is it fair to	18	A. We did not make our preclinical	
19	conclude, Doctor, that you didn't analyze the	19	experimental studies to this topic, but I	
20	mesh that's on in the photograph on	20	know that my clinical colleagues made some	
21	Figure 9 B on page 31 of your report to	21	ultrasound investigation looking into the	
22	determine the extent to which the mesh	22	slings that Dr. Tunn in Berlin has done it,	
23	contracted?	23	that there is there are some references	
24	MR. ANDERSON: Objection.	24	showing that you can that you can analyze	
	Page 439		Page 4	441
1	Go ahead.	1	the degree of contraction in patients as well	
2	THE WITNESS: I didn't analyze	2	and that you find there some narrowing of the	
3	it on the basis of this microscopical	3	width of the sling.	
4	image.	4	Q. Have your clinical colleagues	
5	QUESTIONS BY MR. THOMAS:	5	published any study describing their	
6	Q. Do you have an opinion to a	6	experience of contraction?	
7	reasonable degree of scientific certainty	7	A. There has been a presentation,	
8	that Ethicon TVT® mesh used for the treatment	8	I think, at an international Congress and at	
9	of stress urinary incontinence contracts	9	the at a German conference where they	
10	after implantation?	10	presented their results.	
11	A. To make it clear in advance, I	11	Q. Do you know if the results that	
12	know that polymer itself does not contract	12	your clinical colleagues found have been	
13	and polypropylene does not contract itself.	13	published anywhere outside of this	
14	It is contraction of the wound area. It's a	14	presentation?	
15	contraction of the collagen. It is a change	15	A. At least the European or the	
16	of the tissue there. To be clear in this	16	international abstract has been published in	
17	field, otherwise everyone can say a plastic	17	the supplements there.	
18	sheet doesn't contract.	18	Q. Who are your colleagues so if I	
19	So in this regard that the scar	19	wanted to find that abstract I could find it?	
20	shows some contraction and with this scar	20	A. Professor Kirschner-Hermanns,	
21	contracts the mesh, yes, it depends. In	21	was a coauthor, Dr. Najjari, she made the	
22	principle, the extent of contraction is	22	study.	
23	related to the extent of scar formation and	23	Q. Do you cite that abstract in	
24	Prolene® induces a lot of scar formation and,	24	your report?	

26 (Pages 438 to 441)

	Page 442		Page 444
1	You know, I don't need to know.	1	of medical and scientific certainty that the
2	You mentioned some work by	2	Prolene® mesh in Ethicon's TVT® products
3	Dr. Tunn in this area.	3	contracts or shrinks 30 to 50 percent after
4	A. Dr. Tunn, yeah. We call it	4	implantation.
5	he has published studies using ultrasound	5	Is that correct? Did I read
6	looking what happens to meshes there, and I	6	that correctly?
7	think it was it were one of the first	7	A. Yes.
8	articles published showing that there is this	8	Q. Does that mean that every mesh
9	change of the mesh structure which was quite	9	implanted in a woman for the treatment of
10	common in hernia surgery, we know it ten	10	stress urinary incontinence is going to
11	years longer, but for the urogynecologists,	11	shrink at least 30 percent?
12	it was a new message at that time, I believe.	12	A. No, that is that is not
13	Q. Now, was his study published in	13	that is not correct. I wouldn't expect this.
14	a journal?	14	We know that from all of these preclinical
15	A. It was published in a journal.	15	and clinical studies that has been done to
16	I don't recall precisely whether he was	16	address the issue of shrinkage, it, of
17	focused on meshes, the flat meshes, the	17	course, is influenced by the textile
18	Prolift® things, or whether he really looked	18	structure, but it is influenced by the
19	to the slings or whether he combined it. I	19	surgical trauma as well, which leads to scar,
20	don't recall the details any longer, but he	20	which leads to a contraction of this area.
21	showed very clearly that using a textile in	21	So even the best mesh which
22	the pelvic floor as well you have these	22	probably does not induce any inflammation in
23	changes what we have seen in hernia surgery	23	this field will be in an area of scar that
24	years ago.	24	shows a contraction of about 15, 20 percent,
	Page 443		Page 445
1	Q. Do you recall the extent to	1	if you have extended scar tissue. If you
2	which Dr. Tunn found contraction in the study	2	have a laparoscopic procedure where the
3	that he conducted?	3	surgical trauma is minimized, this can be
4	A. Significantly. 50 percent or	4	less than 20 percent. When you have an open
5	more.	5	surgical trauma there, it should be in around
6	Q. And when you say "50 percent or	6	20 percent. I would expect that this is a
7	more," does that mean that the tissues	7	range that will be very hard to come below
8	surrounding the mesh basically shrinks in	8	this range.
9	half?	9	Q. For any
10	A. That is a good point because	10	A. Everything yeah, it is a
11	there is a mixup of all of these things.	11	consequence of the surgery and of scar. If
12	Whether it's a reduction of the area of	12	you create some scar, you have it. If you
13	50 percent, then you have a smaller reduction	13	produce a lot of scar, this shrinkage rate
14	in the lengths and in the sides. So	14	can go up to 80 or 90 percent.
15	sometimes they in the literature, it's	15	Q. And when you use figures in
16	they mention the reduction of the lengths,	16	your report of 30 to 50 percent or use
17	not of the area.	17	numbers like you just used a moment ago of 80
18	So it is very often not clear	18	to 90 percent shrinkage, what does that mean?
19 20	about it, but at least in our clinical study,	19	MR. ANDERSON: Other than what
20	they measured the widths of the sling so it	20 21	he's already told you?
22	is clear it is in one dimension.	22	MR. THOMAS: Well, he told me there's a confusion in the literature
23	Q. Okay. Now, on page 33 of your	23	about how it was measured and I want
24	report, in the middle of the page it says, "It also is my opinion to a reasonable degree	24	to know what he means.
<u> 4</u>	it also is my opinion to a reasonable degree	4	to know what he inealls.

27 (Pages 442 to 445)

	Page 446		Page 448
1	MR. ANDERSON: Well, he told	1	understand that based on your training,
2	you more than that, but go ahead.	2	education and experience that the use of mesh
3	THE WITNESS: So we started	3	in any application will induce a shrinkage or
4	when we first made revision operations	4	contracture of 20 percent?
5	and looked to all of these old meshes.	5	A. Not in the meaning that the
6	We took a lot of photographs where we	6	mesh makes a shrinkage of 20 percent. It
7	took the images of the mesh when it	7	depends from the type of mesh. There are
8	was implanted, we got a size of it and	8	some meshes which usually lead to shrinkage
9	then later on at the revision you see	9	that is 30 to 50 to 60 to 80 to 90 percent
10	that only a small a much smaller	10	so.
11	mesh because of the contraction. And	11	Q. I get that.
12	that was the extent of shrinkage at	12	My question is: Is the best
13	that time.	13	that you can do when you use mesh in the
14	Amid at the Suvretta meetings,	14	human body is to have a shrinkage or
15	he reported of a shrinkage rate of 80	15	contracture rate of 20 percent?
16	to 90 percent for the plaques which	16	MR. ANDERSON: Objection.
17	are very big amount of material in a	17	Asked and answered.
18	small place so this is the upper limit	18	Go ahead.
19	80 to 90 percent of this. When we	19	THE WITNESS: As I told you, it
20	made our own experiments where we	20	depends. It's influenced by the
21	tried to figure out and we were still	21	surgical trauma as well. If you have
22	busy to work on it to objectify the	22	a very, very small surgical trauma and
23	extent of the shrinkage under various	23	very little scar formation, there may
24	conditions.	24	be. I can't imagine that you can go
	Page 447		Page 449
1	QUESTIONS BY MR. THOMAS:	1	below this range.
2	Q. Are you currently involved in a	2	QUESTIONS BY MR. THOMAS:
3	study analyzing the extent to which the	3	Q. "This range" being what?
4	tissue around mesh shrinks or contracts?	4	A. Of 20 percent but, yeah.
5	A. Yeah. We have a study in the	5	Q. Okay. In how many patients who
6	groin to look what happens to the mesh	6	receive Ethicon TVT® products do you expect
7	material after one year and specifically with	7	to see a shrinkage rate of 30 percent?
8	the focus on shrinkage.	8	A. You cannot answer. It depends
9	Q. Okay. And we talked about that	9	from the time period. It depends from the
10	yesterday?	10	conditions of the OR. It depends whether
11	A. Yeah.	11	there is a contamination with bacteria. It
12	Q. Have you ever conducted a study	12	depends from the degree of the inflammatory
13	to determine the extent to which the tissues	13	process. So hopefully the number is quite
14	surrounding mesh after implantation for the	14	low, but even if it's low, if it's not
15	treatment of stress urinary incontinence	15	necessary, it should be avoided.
16	contracts?	16	Q. In how many patients who
17	A. We did a lot of these studies	17	receive Ethicon mesh for the treatment of
18	with Prolene®, with Marlex, which is the mesh	18	stress urinary incontinence would you expect
19	that is used for the treatment of.	19	to see a shrinkage or contracture of
20	Q. I'm talking I am sorry.	20	50 percent after implantation?
21	A. But we didn't make specific	21	A. I can't give you a figure.
22	analysis which reflects the treatment with a	22	Q. Is that a common finding, a
23	sling in the pelvic.	23	rare finding? Do you have any kind of range
24	Q. Okay. So is it fair to	24	at all to attach to that number?

28 (Pages 446 to 449)

	Page 450		Page 45	52
1	MR. ANDERSON: Objection as to	1	THE WITNESS: No, it doesn't	
2	form.	2	depend on it. It is influenced on.	- 1
3	Go ahead.	3	So you can create some pain just by	- 1
4	THE WITNESS: Again, it depends	4	surgery. You don't need a mesh to	- 1
5	from the subgroup which you analyze	5	create some pain. But if you have an	- 1
6	and the time period. If you're	6	excellent surgery, excellent patient	- 1
7	looking after two months, then you	7	and then you get a pain, then maybe it	- 1
8	will not expect a significant	8	can be a problem of the mesh.	- 1
9	shrinkage due to wound contraction and	9	QUESTIONS BY MR. THOMAS:	- 1
10	therefore, the function may be very	10	Q. Well, my point is you discuss	- 1
11	well.	11	with the patient who is considering whether	- 1
12	If you're going to if you're	12	to have mesh implanted for hernia the fact	- 1
13	looking at two years, three years and	13	that this mesh will contract and it may cause	- 1
14	you have a patient with increased	14	complications?	- 1
15	problems in this area due to the	15	A. Yes, but we are able to tell	- 1
16	scarring process, then the likelihood	16	them that we are using mesh material where	- 1
17	of finding a shrinkage is well	17	this risks has been minimized.	- 1
18	considerably higher.	18	Q. Okay. And to the extent that	- 1
19	If you look to all of the	19	you're using a heavy-weight, small pore mesh	- 1
20	patients that you are you have to	20	for those repairs where still appropriate,	- 1
21	think about in the moment. In this	21	you would have the same conversation,	- 1
22	subgroup, I expect that the rate of	22	wouldn't you?	- 1
23	the significant shrinkage is much	23	A. Similar conversation, but	- 1
24	higher than in those who doesn't have	24	another list of risks and benefits.	- 1
	Page 451		Page 45	53
1	any problems.	1	Q. What are the complications that	
2	QUESTIONS BY MR. THOMAS:	2	you associate with shrinkage?	
3	Q. Doctor, is it fair to	3		
			A. Shrinkage?	
4	understand that mesh shrinkage or contracture	4	A. Shrinkage? It is a considerably stiffening	
5	understand that mesh shrinkage or contracture does not always lead to patient	l .	It is a considerably stiffening	
		4		
5	does not always lead to patient	4 5	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so	
5 6 7 8	does not always lead to patient complications?	4 5 6	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that	
5 6 7 8 9	does not always lead to patient complications?  A. I would expect that there isn't	4 5 6 7	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to	
5 6 7 8 9	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is	4 5 6 7 8 9	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or	
5 6 7 8 9 10	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an	4 5 6 7 8 9 10	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of	
5 6 7 8 9 10 11	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.	4 5 6 7 8 9 10 11	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very	
5 6 7 8 9 10 11 12 13	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.  Q. And when you performed hernia	4 5 6 7 8 9 10 11 12 13	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes	
5 6 7 8 9 10 11 12 13 14	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.  Q. And when you performed hernia surgery, you understood that your mesh would	4 5 6 7 8 9 10 11 12 13	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes complaints and pain just by restricting the	
5 6 7 8 9 10 11 12 13 14 15	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.  Q. And when you performed hernia surgery, you understood that your mesh would shrink or contract, fair?	4 5 6 7 8 9 10 11 12 13 14 15	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes complaints and pain just by restricting the mobility of the tissue. It expresses huge	
5 6 7 8 9 10 11 12 13 14 15 16	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.  Q. And when you performed hernia surgery, you understood that your mesh would shrink or contract, fair?  A. I expected a shrinkage of this	4 5 6 7 8 9 10 11 12 13 14 15	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes complaints and pain just by restricting the mobility of the tissue. It expresses huge intensity of scar formation in this area so	
5 6 7 8 9 10 11 12 13 14 15 16 17	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.  Q. And when you performed hernia surgery, you understood that your mesh would shrink or contract, fair?  A. I expected a shrinkage of this area to some degree in every patient, yes.	4 5 6 7 8 9 10 11 12 13 14 15 16 17	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes complaints and pain just by restricting the mobility of the tissue. It expresses huge intensity of scar formation in this area so there is a high risk of getting entrapped	
5 6 7 8 9 10 11 12 13 14 15 16 17	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.  Q. And when you performed hernia surgery, you understood that your mesh would shrink or contract, fair?  A. I expected a shrinkage of this area to some degree in every patient, yes.  Q. And the extent to which that	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes complaints and pain just by restricting the mobility of the tissue. It expresses huge intensity of scar formation in this area so there is a high risk of getting entrapped nerves in this scar formation. It reduces	
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.  Q. And when you performed hernia surgery, you understood that your mesh would shrink or contract, fair?  A. I expected a shrinkage of this area to some degree in every patient, yes.  Q. And the extent to which that shrinkage or contracture caused any	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes complaints and pain just by restricting the mobility of the tissue. It expresses huge intensity of scar formation in this area so there is a high risk of getting entrapped nerves in this scar formation. It reduces the area of the mesh material. In the field	
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.  Q. And when you performed hernia surgery, you understood that your mesh would shrink or contract, fair?  A. I expected a shrinkage of this area to some degree in every patient, yes.  Q. And the extent to which that shrinkage or contracture caused any complication in the patient depends on the	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes complaints and pain just by restricting the mobility of the tissue. It expresses huge intensity of scar formation in this area so there is a high risk of getting entrapped nerves in this scar formation. It reduces the area of the mesh material. In the field of hernia surgery, you expect that the	
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.  Q. And when you performed hernia surgery, you understood that your mesh would shrink or contract, fair?  A. I expected a shrinkage of this area to some degree in every patient, yes.  Q. And the extent to which that shrinkage or contracture caused any complication in the patient depends on the surgeon's skill and the specific	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes complaints and pain just by restricting the mobility of the tissue. It expresses huge intensity of scar formation in this area so there is a high risk of getting entrapped nerves in this scar formation. It reduces the area of the mesh material. In the field of hernia surgery, you expect that the overlap is decreased and, therefore, the	
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.  Q. And when you performed hernia surgery, you understood that your mesh would shrink or contract, fair?  A. I expected a shrinkage of this area to some degree in every patient, yes.  Q. And the extent to which that shrinkage or contracture caused any complication in the patient depends on the surgeon's skill and the specific comorbidities of the plaintiff excuse me,	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes complaints and pain just by restricting the mobility of the tissue. It expresses huge intensity of scar formation in this area so there is a high risk of getting entrapped nerves in this scar formation. It reduces the area of the mesh material. In the field of hernia surgery, you expect that the overlap is decreased and, therefore, the increase for recurrence is higher.	
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	does not always lead to patient complications?  A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.  Q. And when you performed hernia surgery, you understood that your mesh would shrink or contract, fair?  A. I expected a shrinkage of this area to some degree in every patient, yes.  Q. And the extent to which that shrinkage or contracture caused any complication in the patient depends on the surgeon's skill and the specific	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes complaints and pain just by restricting the mobility of the tissue. It expresses huge intensity of scar formation in this area so there is a high risk of getting entrapped nerves in this scar formation. It reduces the area of the mesh material. In the field of hernia surgery, you expect that the overlap is decreased and, therefore, the	

29 (Pages 450 to 453)

	Page 454		Page 456
1	withstand some forces, then you have a higher	1	the figures.
2	pressure to the cells because the contact	2	QUESTIONS BY MR. THOMAS:
3	area is reduced. Shrinkage means that you	3	Q. Okay. Doctor, do you have an
4	have an accumulation of material at a	4	opinion about the extent to which mesh
5	specific area so even the large pore	5	contracture or shrinkage in patients who are
6	constructions will change and switch to small	6	being treated for stress urinary incontinence
7	pore constructions. This may be some.	7	impacts the cure for stress urinary
8	Q. Do you have any idea of the	8	incontinence?
9	rate of complications that are reported due	9	
10		10	MR. ANDERSON: Objection to form.
11	to contracture or shrinkage in the placement	11	
12	of mesh for the treatment of stress urinary incontinence?	12	THE WITNESS: It depends from
13			the subgroup you're analyzing. If
	A. We had some figures where we	13	you're analyzing the patients that
14	can where we can estimate the increase of	14	complains afterwards, you will find a
15	risk for pain for these heavy-weight, small	15	significant ratio of patient that
16	pore meshes as Marlex, as Prolene®, which	16	suffered from shrinkage and,
17	were used for the treatment of incontinence.	17	therefore, developed these
18	Q. Marlex is not used for the	18	complications.
19	treatment of stress urinary incontinence, is	19	QUESTIONS BY MR. THOMAS:
20	it?	20	Q. When you say "complaints," what
21	A. As these meshes that are used,	21	kind of complaints are you talking about?
22	Marlex, no, it's not used. But these are	22	A. Pain, dysfunction of the
23	these are the group of meshes and Prolene® is	23	bladder.
24	one of the meshes that is used.	24	Q. Now, just so
	Page 455		D 457
	1 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		Page 457
1	I'm not sure whether you are	1	A. Erosions.
1 2		1 2	
	I'm not sure whether you are		A. Erosions.
2	I'm not sure whether you are sticking on the specific situation in the	2	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is
2 3	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on	2 3	<ul><li>A. Erosions.</li><li>Q. Just so we're clear, the</li></ul>
2 3 4	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is	2 3 4	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder
2 3 4 5	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a	2 3 4 5	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that
2 3 4 5 6	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can	2 3 4 5 6	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair?
2 3 4 5 6 7	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.	2 3 4 5 6 7	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that.
2 3 4 5 6 7 8	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically	2 3 4 5 6 7 8	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary
2 3 4 5 6 7 8 9	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for	2 3 4 5 6 7 8	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the
2 3 4 5 6 7 8 9 10	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence	2 3 4 5 6 7 8 9	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine?
2 3 4 5 6 7 8 9 10 11 12	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of	2 3 4 5 6 7 8 9 10	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine? A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to	2 3 4 5 6 7 8 9 10 11 12 13	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine? A. Yes. Q. With that goal of the treatment
2 3 4 5 6 7 8 9 10 11 12 13	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of	2 3 4 5 6 7 8 9 10 11 12 13 14	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine? A. Yes. Q. With that goal of the treatment in mind, does mesh contracture or shrinkage
2 3 4 5 6 7 8 9 10 11 12 13 14 15	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary	2 3 4 5 6 7 8 9 10 11 12 13	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine? A. Yes. Q. With that goal of the treatment in mind, does mesh contracture or shrinkage have any impact on the ability of the mesh to
2 3 4 5 6 7 8 9 10 11 12 13	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine? A. Yes. Q. With that goal of the treatment in mind, does mesh contracture or shrinkage have any impact on the ability of the mesh to treat that condition?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence?  MR. ANDERSON: Objection.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine? A. Yes. Q. With that goal of the treatment in mind, does mesh contracture or shrinkage have any impact on the ability of the mesh to treat that condition? A. Shrinkage, from my opinion,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence?  MR. ANDERSON: Objection.  Asked and answered.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine? A. Yes. Q. With that goal of the treatment in mind, does mesh contracture or shrinkage have any impact on the ability of the mesh to treat that condition? A. Shrinkage, from my opinion, will be one reason or is a fact that reflects
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence?  MR. ANDERSON: Objection.  Asked and answered.  Go ahead.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine? A. Yes. Q. With that goal of the treatment in mind, does mesh contracture or shrinkage have any impact on the ability of the mesh to treat that condition? A. Shrinkage, from my opinion, will be one reason or is a fact that reflects the extent of scar formation and this will be
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence?  MR. ANDERSON: Objection.  Asked and answered.  Go ahead.  THE WITNESS: Independent from	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine? A. Yes. Q. With that goal of the treatment in mind, does mesh contracture or shrinkage have any impact on the ability of the mesh to treat that condition? A. Shrinkage, from my opinion, will be one reason or is a fact that reflects the extent of scar formation and this will be one reason for bad results of this procedure.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence?  MR. ANDERSON: Objection.  Asked and answered.  Go ahead.  THE WITNESS: Independent from the mesh material, if you wanted to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine? A. Yes. Q. With that goal of the treatment in mind, does mesh contracture or shrinkage have any impact on the ability of the mesh to treat that condition? A. Shrinkage, from my opinion, will be one reason or is a fact that reflects the extent of scar formation and this will be one reason for bad results of this procedure. Q. And when you say "bad results,"
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence?  MR. ANDERSON: Objection.  Asked and answered.  Go ahead.  THE WITNESS: Independent from the mesh material, if you wanted to know some figures of the patients	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine? A. Yes. Q. With that goal of the treatment in mind, does mesh contracture or shrinkage have any impact on the ability of the mesh to treat that condition? A. Shrinkage, from my opinion, will be one reason or is a fact that reflects the extent of scar formation and this will be one reason for bad results of this procedure. Q. And when you say "bad results," in terms of the ultimate goal of treating the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.  Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence?  MR. ANDERSON: Objection.  Asked and answered.  Go ahead.  THE WITNESS: Independent from the mesh material, if you wanted to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Erosions. Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair? A. What? Q. Strike that. The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine? A. Yes. Q. With that goal of the treatment in mind, does mesh contracture or shrinkage have any impact on the ability of the mesh to treat that condition? A. Shrinkage, from my opinion, will be one reason or is a fact that reflects the extent of scar formation and this will be one reason for bad results of this procedure. Q. And when you say "bad results,"

30 (Pages 454 to 457)

	Page 458		Page 460
1	MR. ANDERSON: Objection to	1	complex system, and if you have a very strict
2	form.	2	scar there that may be too small, that this
3	THE WITNESS: I didn't I	3	impairs the dynamic of the pelvic floor
4	didn't understand what comparison you	4	significantly and, therefore, the function of
5	want to have.	5	all of the organs that are in the pelvic
6	QUESTIONS BY MR. THOMAS:	6	floor.
7	Q. Well, we understand the goal of	7	MR. ANDERSON: It's my turn to
8	using mesh to treat stress urinary	8	take a break.
9	incontinence is to manage the involuntary	9	MR. THOMAS: Sure.
10	discharge of urine, correct?	10	(Off the record at 11:23 a.m.)
11	A. Yes.	11	QUESTIONS BY MR. THOMAS:
12	Q. If you have mesh contracture or	12	Q. Doctor, during the development
13	shrinkage, how does that impact what the mesh	13	of VYPRO I, did you have any involvement in
14	does to treat the involuntary discharge of	14	the biocapability analysis of VYPRO I?
15	urine?	15	A. Yes.
16	A. If you have a significant	16	Q. And were there tests conducted
17	shrinkage, a significant scar formation in	17	on VYPRO I for carcinogenicity, for example?
18	this area, then you can have pain, you can	18	A. If you think if you're
19	have a increase or migration and erosion	19	thinking of some in vitro tests for I do
20	of the urethra. You can have erosion in the	20	not recall whether these tests have been done
21	vagina.	21	in Aachen.
22	So all of these things can be	22	If you're thinking of the
23	the consequence of scar formation and	23	general discussion about whether there is a
24	shrinkage in this field.	24	risk for cancer when using textiles, we made
24		24	
	Page 459		Page 461
1	QUESTIONS BY MR. THOMAS:	1	investigations.
2	Q. Do you know whether mesh	2	Q. Okay. Did you make
3	contracture or shrinkage impacts the ability	3	investigations strike that.
4	of the patient receiving the mesh to control	4	Do you recall conducting any in
5	her urine?	5	vitro testing for VYPRO I?
6	A. I didn't please rephrase it.	6	A. In vitro testing we did it for
7	Q. Do you know whether mesh	7	the attachment of bacteria. We did it for
8	contracture or shrinkage controls strike	8	the for the we did it in a setting
9	that.	9	where we looked what happens to the
10	Do you know whether mesh	10	fibroblasts when growing together with meshes
11	contracture or shrinkage impacts the ability	11	in vitro. That has been our studies, yeah.
12	of the patient receiving the mesh to control	12	Q. Did you conduct any
13	her urine?	13	cytotoxicity testing for VYPRO I?
14	A. I expect that considerable	14	A. Not that I recall.
15	shrinkage of the mesh can in some patients	15	Q. Do you recall learning that
16	lead to the or to a recurrence of the	16	VYPRO I tested positive for cytotoxicity in
17	incontinence.	17	vitro?
18	Q. Okay. So you would expect the	18	MR. ANDERSON: Objection.
19	incontinence to return. Mechanistically, how	19	Based on his prior answer.
20	does that happen?	20	Go ahead.
21	A. I have the impression that	21	THE WITNESS: I recall that
$\sim$	we're back some two hours ago. There is a	22	somewhere in the documents there has
22			
22 23 24	complex interaction between the ligaments, the muscles of the pelvic floor. It's a very	23 24	been some there has been done some in vitro cytotoxicity tests indicating

31 (Pages 458 to 461)

	Page 462		Page 464
1	that polypropylene has some problems,	1	this study that is done by our gynecologist,
2	but I do not recall any specific	2	Dr. Najjari, who made ultrasound
3	investigations to the VYPRO that is	3	investigation comparing two different slings,
4	done in Aachen. I'm sure it will be	4	one of polypropylene and one of PVDF, and
5	done or it was done in Hamburg Ethicon	5	they presented these results in this abstract
6	because it's required before launching	6	that has been published in this supplement
7	a product to the market.	7	article.
8	QUESTIONS BY MR. THOMAS:	8	Q. Other than that study that you
9	Q. And my question is simply this:	9	just described, since your last deposition in
10	Whether you did the testing or not, did you	10	October 2012, are you aware of any clinical
11	ever learn from any source that VYPRO I	11	studies that compare the use of PVDF to the
12	tested positive for cytotoxicity in vitro	12	use of polypropylene in any application to
13	during the biocompatibility analysis?	13	determine which is better?
14	A. Not that I recall.	14	A. No, I don't recall any clinical
15	Q. About an hour ago, maybe more,	15	study.
16	you mentioned a recent study in the last year	16	Q. Doctor, what have you done to
17	involving PVDF mesh and I thought I	17	analyze the forces that are placed upon mesh
18	understood you to say it was a comparative	18	used for the treatment of stress urinary
19	study.	19	incontinence?
20	Do you recall that testimony?	20	A. It started with our efforts to
21	A. I mentioned a study with PVDF?	21	get a first impression about forces to the
22	Q. And I want to say, my notes are	22	mesh materials in principle, how to define
23	very sketchy on it, I tried to write it down	23	it, how to measure it, how to get a range, a
24	so I could remember, but I thought it was a	24	figure out, and these efforts started in 1993
	Page 463		Page 465
1	comparative study involving PVDF meshes	1	with this question. And in 1994, we started
2	perhaps out of Berlin.	2	to think about how to define the forces, the
3	MR. ANDERSON: He's asking you	3	requirements to the textiles for the
4	if earlier in your testimony did	4	reenforcement in tissues.
5	you were you talking about some	5	So that was the that is the
6	comparative study involving PVDF	6	rough experience that we got during all these
7	meshes out of Berlin.	7	years that we got an impression of the range
8	THE WITNESS: In the pelvic	8	and what can be considered as over engineered
9	floor?	9	and whatnot.
10	QUESTIONS BY MR. THOMAS:	10	In 2005, '6, the upcoming
11	Q. Anywhere. Pelvic floor,	11	question was what are the biomechanical
12	hernia, I'm not sure.	12	properties to the pelvic floor and we tried
13	A. Comparative in the meaning that	13	to or we made we looked very careful to
14	you compared different materials and one of	14	the literature, Cosson and all of these
15	it is PVDF?	15	expressed what they are considering for the
16	Q. Yes.	16	use in the pelvic floor and so we tried to
17	A. No, I don't recall any clinical	17	combine all of this knowledge to get an
18	study.	18	impression.
19	Q. Okay. Since your deposition	19	Q. Okay. So what specifically
20	last year, are you aware of any clinical	20	have you done to analyze the forces that are
21	studies that compare the risks and	21	placed upon mesh used for the treatment of
22	complications associated between PVDF and	22	stress urinary incontinence?
23	polypropylene?	23	A. As I tried to answer it before,
24	A. Now I got it. You may refer to	24	we analyzed a lot of these data that have

32 (Pages 462 to 465)

	Page 466		Page 468
1	been there. We analyzed very careful the	1	forces, what is elasticity that can be done
2	difficulties to find a good equipment, a good	2	there.
3	setting, to come to a specific data there.	3	So a lot of various things to
4	And finally we got an impression about the	4	get a closer idea about the biomechanics of
5	biomechanics, the differences of the	5	the pelvis.
6	biomechanics between the pelvic floor and the	6	Q. What specifically have you done
7	abdominal wall. We didn't do any specific	7	to measure the forces that are applied to
8	measurements as Cosson did, yeah.	8	mesh that are used for the treatment of
9	Q. When you're talking about	9	stress urinary incontinence?
10	forces in the pelvic floor, are you talking	10	A. We never made direct
11	about forces that occur in the pelvic floor	11	measurements of the forces.
12	in the management of pelvic organ prolapse?	12	Q. Have you reached any opinions
13	A. It is not limited to the	13	about the nature and the extent of the force
14	pelvic it is not limited to the prolapse.	14	that's applied to the mesh used for the
15	It is when we have been studying the	15	treatment of stress urinary incontinence?
16	biomechanics of the pelvic floor, what	16	A. So in conclusion of all
17	happens there, the intention of this was to	17	these our experiences and all of the
18	define what may be the requirements of the	18	literature there, it is it is I'm sure
19	textile in regard to stability. That was the	19	it is in a range that is far below the
20	purpose for this. Not to simulate or to	20	tensile strength that is required for the
21	reflect the situation there and, therefore,	21	abdominal wall so it is less about 10 newton
22	we focused mainly on some forces per	22	per centimeters. Yeah, less than 10 newton
23	centimeters and, yeah, we know that there	23	per centimeters I would expect.
24	are or I know that there is a that it's	24	Q. And when you say 10 newtons per
	Page 467		Page 469
1	very difficult to define really the	1	centimeter, what does that measure?
2	biomechanics in the pelvic floor. It is	2	A. That means that's the force per
3	impossible to get all aspects there.	3	centimeter of the textile. I know there's a
4	So force is one aspect, but we	4	mixing up, and I recall a very precise
5	focused on the force what is important for	5	summary of this mixing up by Professor
6	the characterization of the mesh material, of	6	Williams. At the last deposition, he made an
7	the textiles there.	7	expert report where he summarized the mixing
8	Q. And what forces did you study	8	up of pressures force per centimeters and
9	to determine the requirements for textiles in	9	forces, per se. That cannot be interfered or
10	the pelvic floor, what forces did you study?	10	that cannot be exchanged so this figure is
11	A. The forces the basis of	11	limited to newton per centimeter, that means
12	our of my opinion about the it is based	12	per centimeter of mesh in the width end or
13	on the experience that tissue has some	13	tissue.
14	limited ability to withstand some forces so	14	Q. And when you speak about force,
15	any repair has to consider that the	15	in what direction is it applied?
16	surrounding tissue is limited in this field.	16	A. It's a uniaxial force.
17	You have to consider some	17	Q. And from what direction is it
18	intraabdominal pressure, that you have to	18	applied?
19	consider some flexibility of the anatomic	19	MR. ANDERSON: Objection to
20	structures. We have made some measurements	20	form.
21	tearing out looking at what is the resistance	21	THE WITNESS: It is a first
22	of tissues to extract meshes or sutures or	22	of all, it is an abstract direction
23	anchors what are the forces there. We made	23	yeah. No, it's theoretical assumption
24	some analysis of textile structures, what are	24	without having a specific direction.

33 (Pages 466 to 469)

	Page 470		Page 472
1	When you estimate the tensile	1	under stress may help to improve
2	strengths that is necessary to	2	biocompatibility of textile implants."
3	reinforce abdominal wall of the pelvic	3	Has there been any further in
4	floor, there is no specific direction.	4	vitro have there been any further in vivo
5	If you made a measurement at the	5	studies to investigate whether the
6	textile, indeed you have to make	6	preservation of a high effective porosity
7	separate analysis in meshing direction	7	under stress may help to improve the
8	and perpendicular to the machine	8	biocompatibility of textile implants?
9	direction then you will get different	9	A. Can I have a look?
10	results.	10	As we discussed yesterday,
11	But to define the an	11	the a difficult or an important point is
12	estimate of the maximum of the	12	to identify the impact of these effective
13	requirement maximum or minimum	13	porosity on the clinical outcome, how to
14	requirements, then there is no	14	identify this. And, yes, indeed there we
15	direction.	15	meanwhile know that there are various mesh
16	QUESTIONS BY MR. THOMAS:	16	materials. We try to get precise data of the
17	Q. Okay. You said a moment ago	17	effective porosity of the various kinds of
18	that the force was uniaxial.	18	materials and we want to analyze registries
19	What do you mean by that?	19	in regard to these properties of the mesh
20	A. Uniaxial is the experimental	20	materials. These are the studies we're
21	setting that you fix the mesh or the	21	working on in the moment. So, yes, there are
22	sample tissue sample or mesh sample on one	22	attempts to make clinical studies.
23	side and your tearing on the other and then	23	Q. But there haven't been any
24	you get a force. And if it's a stripe with	24	published yet
	Page 471		Page 473
1	widths of 1 centimeter, you get some figure.	1	A. No. No. No.
2	If it's 2 centimeters, you get another	2	Q. Let me get my question out.
3	figure.	3	A. Yes.
4	To easy up the comparison of	4	Q. There haven't been any
5	different structures, later on it is	5	studies strike that.
6	normalized to a width of 1 centimeter,	6	There haven't been any in vivo
7	though, in fact, these measurements are all	7	studies which investigate whether the
8	done at various widths of the sample size, 4	8	preservation of a high effective porosity
9	centimeters, 5 centimeters. There are	9	under stress may help to improve the
10	different standards. Usually it's described	10	biocompatibility of textile implants; is that
11	in the material and methods.	11	correct?
12	Q. And the uniaxial testing you're	12	A. Yes.
13	describing now, is that used by yourself and	13	Q. Now, we talked earlier about
14	Dr. Mühl in your study, Exhibit 20; is that	14	how the mesh is placed in the body.
15	correct?	15	It's not anchored or secured on
16	A. This uniaxial testing is part	16	either end?
17	of these measurements of Professor Mühl, but	17	A. That is correct.
18	we started in 1994 with our first textile	18	Q. And the way the mesh holds its
19	analysis to provide this data.	19	position in the body is by the tissue moving
20	Q. Back in 2008, 2007, when	20	through the pores and anchoring the pores,
21	Exhibit Number 20 was published, the last	21	correct?
22	sentence of the abstract says, "Further, in	22	A. If you restrict it to the time
23	vivo studies have to investigate whether the	23	period directly after the operation, this is
24	preservation of a high effective porosity	24	for the first seconds or minutes, this is the
	preservation of a night effective polosity	4	for the first seconds of fillingtes, this is the

34 (Pages 470 to 473)

1 major mechanism, I suppose. Later on, it 2 will be replaced by others. 3 Q. When there are forces applied 4 to the mesh after implantation, the mesh can 5 move with the forces, can't it? 6 A. If you apply some forces to a 7 mesh, then, first of all, you have some 8 sheering stress at the area where the forces 9 is applied. 10 So the assumption that the 11 entire mesh as a block moves accordingly to 12 some forces somewhere, I think this is not a 13 true, realistic image. 14 Q. Okay. In hernia repair, you 15 often anchor the mesh, suture it; is that 16 fair? 17 A. Fixation of meshes for  1 any precise measurements of this that doc 2 not interfere with the with the procedur 3 In general, you have to expect 4 that by the movement of the urethra, by s 5 physiological movements, standing up or 6 pressing or so, or the movements of the 7 pelvic floor, that you have some shifting 8 the position of these of these organs in 9 relation to other to the bony structures. 10 And this shifting, this 11 mobility, this movements, they will lead some locally forces. 12 Q. And those forces will come fror multiple directions, won't they? 15 A. Always. Always they will come for multiple directions, from all three directions, but to get a good estimate to g	e. ome of	
2 will be replaced by others. 3 Q. When there are forces applied 4 to the mesh after implantation, the mesh can 5 move with the forces, can't it? 6 A. If you apply some forces to a 7 mesh, then, first of all, you have some 8 sheering stress at the area where the forces 9 is applied. 10 So the assumption that the 11 entire mesh as a block moves accordingly to 12 some forces somewhere, I think this is not a 13 true, realistic image. 14 Q. Okay. In hernia repair, you 15 often anchor the mesh, suture it; is that 16 fair?  2 not interfere with the with the procedur 3 In general, you have to expect 4 that by the movement of the urethra, by s 6 physiological movements, standing up or 6 pressing or so, or the movements of the 7 pelvic floor, that you have some shifting 8 the position of these of these organs in 9 relation to other to the bony structures. 10 And this shifting, this 11 mobility, this movements, they will lead 12 some locally forces. 13 Q. And those forces will come fror 14 Q. Okay. In hernia repair, you 15 often anchor the mesh, suture it; is that 16 fair? 18 A. Always. Always they will come 19 relation to other to the bony structures. 10 And this shifting, this 11 mobility, this movements, they will lead 12 some locally forces. 13 Q. And those forces will come fror 14 A. Always. Always they will come 15 A. Always. Always they will come	e. ome of	
Q. When there are forces applied to the mesh after implantation, the mesh can move with the forces, can't it?  A. If you apply some forces to a mesh, then, first of all, you have some sheering stress at the area where the forces is applied.  So the assumption that the entire mesh as a block moves accordingly to some forces somewhere, I think this is not a true, realistic image.  Q. Okay. In hernia repair, you  G. Okay. In hernia repair, you fair?  In general, you have to expect that by the movement of the urethra, by so physiological movements, standing up or pressing or so, or the movements of the pelvic floor, that you have some shifting the position of these of these organs in relation to other to the bony structures.  And this shifting, this mobility, this movements, they will lead some locally forces.  Q. And those forces will come fror multiple directions, won't they? A. Always. Always they will come for to from all directions, from all three	ome of	
to the mesh after implantation, the mesh can move with the forces, can't it?  A. If you apply some forces to a mesh, then, first of all, you have some sheering stress at the area where the forces is applied.  So the assumption that the entire mesh as a block moves accordingly to some forces somewhere, I think this is not a true, realistic image.  Q. Okay. In hernia repair, you fair?  4 that by the movement of the urethra, by s physiological movements, standing up or pressing or so, or the movements of the pressing or so,	of o	
5 move with the forces, can't it? 6 A. If you apply some forces to a 7 mesh, then, first of all, you have some 8 sheering stress at the area where the forces 9 is applied. 10 So the assumption that the 11 entire mesh as a block moves accordingly to 12 some forces somewhere, I think this is not a 13 true, realistic image. 14 Q. Okay. In hernia repair, you 15 often anchor the mesh, suture it; is that 16 fair?  5 physiological movements, standing up or 6 pressing or so, or the movements of the 7 pelvic floor, that you have some shifting 8 the position of these of these organs in 7 relation to other to the bony structures. 10 And this shifting, this 11 mobility, this movements, they will lead 12 some locally forces. 13 Q. And those forces will come fror 14 multiple directions, won't they? 15 A. Always. Always they will come 16 fair? 16 to from all directions, from all three	of o	
6 A. If you apply some forces to a 7 mesh, then, first of all, you have some 8 sheering stress at the area where the forces 9 is applied. 10 So the assumption that the 11 entire mesh as a block moves accordingly to 12 some forces somewhere, I think this is not a 13 true, realistic image. 14 Q. Okay. In hernia repair, you 15 often anchor the mesh, suture it; is that 16 fair?  6 pressing or so, or the movements of the 7 pelvic floor, that you have some shifting 8 the position of these of these organs in 9 relation to other to the bony structures. 10 And this shifting, this 11 mobility, this movements, they will lead 12 some locally forces. 13 Q. And those forces will come fror 14 multiple directions, won't they? 15 A. Always. Always they will come 16 to from all directions, from all three	0	
mesh, then, first of all, you have some sheering stress at the area where the forces is applied.  So the assumption that the entire mesh as a block moves accordingly to some forces somewhere, I think this is not a true, realistic image.  Q. Okay. In hernia repair, you fair?  The pelvic floor, that you have some shifting the position of these of these organs in relation to other to the bony structures. And this shifting, this mobility, this movements, they will lead some locally forces.  Replication to other to the bony structures.  And this shifting, this mobility, this movements, they will lead some locally forces.  Replication to other to the bony structures.  And this shifting, this mobility, this movements, they will lead some locally forces.  Replication to other to the bony structures.  And this shifting, this mobility, this movements, they will lead some locally forces.  Replication to other to the bony structures.  And this shifting, this mobility, this movements, they will lead some locally forces.  And those forces will come from multiple directions, won't they?  A. Always. Always they will come for the position of these of these organs in the position of the p	0	
8 sheering stress at the area where the forces 9 is applied. 10 So the assumption that the 11 entire mesh as a block moves accordingly to 12 some forces somewhere, I think this is not a 13 true, realistic image. 14 Q. Okay. In hernia repair, you 15 often anchor the mesh, suture it; is that 16 fair?  8 the position of these of these organs in 9 relation to other to the bony structures. 10 And this shifting, this 11 mobility, this movements, they will lead some locally forces. 12 some locally forces. 13 Q. And those forces will come from 14 multiple directions, won't they? 15 A. Always. Always they will come 15 to from all directions, from all three	0	
9 relation to other to the bony structures. 10 So the assumption that the 11 entire mesh as a block moves accordingly to 12 some forces somewhere, I think this is not a 13 true, realistic image. 14 Q. Okay. In hernia repair, you 15 often anchor the mesh, suture it; is that 16 fair?  9 relation to other to the bony structures. 10 And this shifting, this 11 mobility, this movements, they will lead some locally forces. 12 some locally forces. 13 Q. And those forces will come from multiple directions, won't they? 15 A. Always. Always they will come for to from all directions, from all three		
So the assumption that the entire mesh as a block moves accordingly to some forces somewhere, I think this is not a true, realistic image.  Q. Okay. In hernia repair, you fair?  And this shifting, this mobility, this movements, they will lead some locally forces. Q. And those forces will come from hultiple directions, won't they?  A. Always. Always they will come fair?  And this shifting, this hultiple directions, they will lead some locally forces. A. Always. Always they will come for the mesh, suture it; is that hultiple directions, from all three		
entire mesh as a block moves accordingly to some forces somewhere, I think this is not a true, realistic image.  12 Some forces somewhere, I think this is not a true, realistic image.  13 C. And those forces will come from the mesh, suture it; is that fair?  14 Okay. In hernia repair, you to from all directions, won't they?  15 A. Always. Always they will come for the mesh, suture it; is that to from all directions, from all three		
some forces somewhere, I think this is not a true, realistic image.  12 some locally forces.  13 Q. And those forces will come from 14 multiple directions, won't they?  15 often anchor the mesh, suture it; is that 16 fair?  10 some locally forces.  11 Q. And those forces will come from 14 multiple directions, won't they?  12 some locally forces.  13 Q. And those forces will come from 14 multiple directions, won't they?  15 A. Always. Always they will come for 15 to from all directions, from all three		
true, realistic image.  13 Q. And those forces will come from 14 Q. Okay. In hernia repair, you 15 often anchor the mesh, suture it; is that 16 fair?  13 Q. And those forces will come from 14 multiple directions, won't they?  15 A. Always. Always they will come 16 to from all directions, from all three		
14 Q. Okay. In hernia repair, you 15 often anchor the mesh, suture it; is that 16 fair?  14 multiple directions, won't they? 15 A. Always. Always they will come to from all directions, from all three		
15 often anchor the mesh, suture it; is that 16 fair?  18 A. Always. Always they will come to from all directions, from all three	L	
16 fair? 16 to from all directions, from all three		
1 ± 7 A. Tiadion of incones for 1 ± 7 unections, but to get a good estimate to g	nt.	
· · · · · · · · · · · · · · · · · · ·	Л	
	iore	
	—	
	age	477
1 which Fibrin glue from Ethicon, for example, 1 A. On our experience, the		
2 that sticks there or fixed there the mesh for 2 literature.		
3 some days or hours. So short-term fixation 3 Q. In hernia repair?		
4 there. 4 A. Textile. Not hernia repair.		
5 It depends on the position. It 5 It's a use of textiles for the reenforcement		
6 depends IPOM mesh usually have to get a 6 of tissues.		
7 fixation. It is a yeah, it is a difficult 7 Q. Okay. Specifically, Doctor,		
8 question there. 8 have you analyzed the forces that are pres	ent	
9 Q. Okay. 9 in the area of the body where the mesh is		
A. It depends on the mesh and on 10 placed for the treatment of stress urinary		
the localization on the patient, on the   11 incontinence?		
12 surgeon. 12 A. Whether I've analyzed these		
Q. Uniaxial loading means just as 13 forces?		
14 you described it. You have one end of the 14 Q. Yes.		
15 mesh stable and you pull the other end,   15 A. Only in the way that I try to		
16 correct? 16 express looking to the literature, looking		
A. It's not necessary that one end 17 to making some measurements at textil	s to	
18 is stable even if you have a textile like   18 see whether it's comparable or not.		
19 this and you're tearing from both sides, it's Q. Can you point me to any		
20 uniaxial. 20 literature or research upon which you rely		
21 Q. Okay. And what are the forces 21 specifically identifying the forces that are		
22 underneath the urethra that cause the 22 present in the area where the mesh is place	ed	
23 uniaxial loading that you've just described? 23 for the treatment of stress urinary		
A. To my knowledge, there isn't 24 incontinence?		

35 (Pages 474 to 477)

	Page 478		Page 480
1	A. I recently found a publication	1	described, did they provide any measurements
2	from 1995, I guess, where they placed at the	2	of the forces in the body at the place where
3	time before TVT®, they at the time, they	3	the mesh is used for the treatment of stress
4	placed fascia slings around the urethra and	4	urinary incontinence?
5	there they measured the force there.	5	A. They made some as I recall,
6	Q. Do you remember the name of	6	they made some estimates of the tensile
7	that study?	7	forces that should be considered for the
8	A. Not at the moment.	8	reenforcement of pelvic floor area.
9	Q. Did you find that information	9	Q. Now, I'm not talking about
10	to be valuable, important to you?	10	reenforcement of pelvic floor.
11	A. It was just recently that I	11	I'm talking very specifically
12	found it, but it was a confirmation of these	12	about mesh placement for the treatment of
13	estimates.	13	stress urinary incontinence.
14	Q. Okay.	14	A. I don't recall that they have a
15	A. Because it was less than these	15	specific chapter dealing with slings.
16	10 newtons.	16	Q. Okay. So we're back to the
17	Q. And do you recall what that	17	1995 study.
18	study that you found looked at and what it	18	Is there any other study to
19	found?	19	which you can point me in support of the
20	A. They measured in patients with	20	your understanding of the forces in the body
21	a device the force at both sides of these	21	at the place where the mesh is used for the
22	fascia sling that the force that was	22	treatment of stress urinary incontinence?
23	-	23	A. There maybe maybe some
24	necessary to make a narrowing of the urethra.  Q. Okay.	24	others, but I don't recall. But these
21	Page 479	21	Page 481
1		1	
1 2	A. So they got an in vivo force there.	1 2	this is to my knowledge, this is the only one who really measured the forces.
3		3	•
4	Q. Okay. So anything other than this 1995 study that you recently reviewed	4	Q. And just so the record is clear, you have not conducted your own
5		5	· · ·
6	upon which you rely for the forces that are	6	analysis of the forces in the body at the place where mesh is used for the treatment of
7	present in the area of the body where mesh is placed for the treatment of stress urinary	7	stress urinary incontinence; is that true?
8	incontinence?	8	A. That is true, I didn't do it.
9	A. Look to a lot of these	9	
10		10	Q. Okay. Now, when you use the term "uniaxial loading," you were referring
11	references, but from my memory, the Deprest working group with Ozon I think Ozon is	11	to forces purely coming from one end to the
12	his name, they presented two, three extended	12	other of the mesh; is that correct?
13	* *	13	A. That is correct.
14	thesis, documents where they presented a lot of data, what they measured and what they	14	Q. Seems to me that if mesh is
15		15	
	calculate, what they estimate.		placed across a woman to support the urethra
16 17	Q. Okay.	16 17	for the treatment of stress urinary
18	<ul><li>A. For the pelvic floor area.</li><li>Q. Okay. Now, did is Cosson,</li></ul>	18	incontinence, that there will be forces from
19		19	the back to the front of the mesh as well; is that true?
20	is that what you said or Deprest?	20	
∠∪	A. Yeah, Cosson made a lot of		MR. ANDERSON: Objection to the
	·	')	
21	measurements at the tissue, but it was from	21	form of that question.
21 22	measurements at the tissue, but it was from Leuven, Deprest, yeah. This working group	22	THE WITNESS: If you're talking
21	measurements at the tissue, but it was from		

36 (Pages 478 to 481)

	Page 482		Page 484
1	There are various forces for the	1	definition means you're pulling on each end,
2	various structures.	2	correct?
3	QUESTIONS BY MR. THOMAS:	3	A. Or you made a fixation at one
4	Q. So the basis of your opinion is	4	end. It is uniaxial, it is just in one
5	that the predominant force is uniaxial; is	5	direction.
6	that fair?	6	Q. And the force that you just
7	A. In a sling, the assumption that	7	described, if you have a mesh in a straight
8	the uniaxial force is an important issue,	8	line, the force that you're describing comes
9	yes, that is true.	9	from above is down on top of the mesh; is
10	Q. Okay. How does the body apply	10	that correct?
11	a uniaxial force to a sling?	11	MR. ANDERSON: Objection.
12	A. If you place in contrast to	12	Form.
13	meshes which are flat meshes with a wide area	13	THE WITNESS: However the
14	of tissue integration, when you make small	14	result is that the sling, the
15	slings, not 20 centimeters, but 1 centimeter,	15	ligament, is stretched.
16	and this is 20-centimeter long there and you	16	QUESTIONS BY MR. THOMAS:
17	made or placed a sling from the lower part of	17	Q. I understand.
18	the pelvis to the skin there, that if you	18	A. And that makes an uniaxial
19	have some movement there in this direction	19	strain.
20	Q. You're moving down?	20	Q. But the force you're describing
21	A. Down, yeah.	21	is not at the end, it's from the top down on
22	If the pelvic floor is going	22	the mesh, correct?
23	downwards, I expect that most of the forces,	23	A. Yes.
24	the strain, is going in the similar direction	24	Q. And so when the force comes
	Page 483		Page 485
1	where the sling is located. And if you	1	down on top of the mesh, there is a force
2	compare the movements going down, they are	2	into the pore structure of the mesh, correct?
3	or they are in relation to the widths of the	3	MR. ANDERSON: Objection.
4	textile, they are they are higher than the	4	Do you understand his question?
5	mobility in these two directions.	5	THE WITNESS: Yeah. Yeah, but
6	Q. Okay.	6	I just in principle, yes, there's
7	A. You only have 1 centimeter of	7	force, but what is the force, how big
8	width. If you have a tensile force trying to	8	is the force. It depends on the
9	make this wider, it's a very small effect.	9	surface, it depends from the cells.
10	Q. Okay. So as I understand your	10	As a scientist, I usually try to then
11	answer, please correct me if I am wrong, a	11	to measure it. I think it is
12	downward force perpendicular to the placement	12	impossible. There is a force, yes,
13	of the mesh will cause a uniaxial loading on	13	but I think it is I'm sure it is
14	the mesh; is that correct?	14	a in an area where it's almost
15	MR. ANDERSON: Objection to	15	impossible to measure because it's so
16	form. Mischaracterizes his testimony.	16	low.
17	THE WITNESS: What I wanted to	17	QUESTIONS BY MR. THOMAS:
18	express is that you place a sling,	18	Q. Let me ask you this question,
19	that the uniaxial strain to this sling	19	Doctor.
20	in the direction of the sling, that is	20	A. And, therefore, not relevant
21	more relevant than the strain from the	21	SO
22	sides.	22	Q. Can you think of a circumstance
23	QUESTIONS BY MR. THOMAS:	23	in the body where a mesh used for the
24	Q. Okay. Uniaxial loading by	24	treatment of stress urinary incontinence is

37 (Pages 482 to 485)

	Page 486		Page 48	8
1	placed under stress by pulling one end	1	So any procedure using textiles	
2	against the other like you do in Exhibit 20?	2	for the replacement of ligaments usually	
3	A. Is placed under stress?	3	mainly has to address uniaxial forces. So	
4	Q. In the same way that you did in	4	textiles replacement of ligaments usually I	
5	the study which is Exhibit 20.	5	think it is very acceptable to reduce this	
6	A. So far I understood is that the	6	to an uniaxial model.	
7	recommendations when implanting these slings,	7	Q. Ligaments have forces and	
8	that this shouldn't be done by applying a	8	stresses in other directions, too, don't	
9	huge amount of tension there. And I don't	9	they?	
10	think that it's a good idea to place a mesh	10	A. As we told, there are always	
11	wherever under tension.	11	forces to some degree from every direction,	
12	Q. So my question is this, Doctor.	12	but they are not significant. They are not	
13	I'm trying to understand whether you can	13	relevant in comparison to the others. That's	
14	identify for me any force in the body that is	14	a reason that you have ligaments and not a	
15	uniaxial in nature that replicates the forces	15	muscle at that position.	
16	that you and Professor Mühl used in your	16	Q. And my question, Doctor, is can	
17	study, Exhibit 20.	17	you describe for me specifically those forces	
18	MR. ANDERSON: By that you mean	18	in the area where mesh is placed for the	
19	uniaxial forces?	19	treatment of stress urinary incontinence that	
20	MR. THOMAS: Yes.	20	replicate this uniaxial loading?	
21	MR. ANDERSON: Okay.	21	MR. ANDERSON: Objection. He	
22	THE WITNESS: Whether I can	22	just answered it.	
23	identify these forces?	23	MR. THOMAS: He used a ligament	
24	10011111 111000 10110001	24	as an example.	
	Page 487		Page 48	9
1	QUESTIONS BY MR. THOMAS:	1	MR. ANDERSON: Yeah.	
2	Q. Yes.	2	THE WITNESS: If you look to	
3	MR. ANDERSON: He said anywhere	3	the book of Petros, yeah, there are	
4	in the body where there are forces	4	some sort of ligaments that are	
5	that are uniaxial, right?	5	stabilizing the urethra, and if you	
6	MR. THOMAS: Okay. Let me ask	6	use a textile as reenforcement of this	
7	the question again.	7	weak structure to treat this patient,	
8	MR. ANDERSON: It's a little	8	yeah, it should be considered as a	
9	confusing. Yeah.	9	replacement of a ligament. And even	
10	QUESTIONS BY MR. THOMAS:	10	from the form, you're dealing now not	
11	Q. My question, Doctor, is this, I	11	with a flat mesh area, but with a 1	
12	think: Can you describe for me forces in the	12	centimeter width. So that is the	
13	area where mesh is placed for the treatment	13	difference. 20 to 1 centimeter.	
14	of stress urinary incontinence that replicate	14	QUESTIONS BY MR. THOMAS:	
15	the forces that are used by you and Dr. Mühl	15	Q. So it's your testimony that the	
16	in your study of effective porosity, which is	16	forces that are applied to the mesh by the	
17	Exhibit 20?	17	body are uniaxial in nature all the time?	
18	A. The first issue is whether	18	MR. ANDERSON: Objection.	
19	there are some uniaxial strain there and if	19	Asked and answered.	
20	you look to the anatomy, you have some	20	THE WITNESS: No, that is not	
21	ligaments. Ligaments usually are thought to	21	correct, not all time.	
22	compensate uniaxial the mechanical strain,	22	It is a justified assumption	
	the biomechanics there, in contrast to some	23	that it gives important information to	- 1
23 24	fascias or muscles there.	24	have this testing in a uniaxial	

38 (Pages 486 to 489)

	Page 490		Page 492
1	direction. It helps us to define	1	certainty that there is no rational reason
2	to define the requirements to a	2	why the TVT® needs the stability and the
3	textile which is intended to replace a	3	amount of material of the Prolene® hernia
4	ligament in this setting and then you	4	mesh which can only be regarded as over
5	have to define the range not to get	5	engineered for this purpose."
6	the risk of being over engineered.	6	Now, we've talked about that at
7	And the Mühl testing just covers	7	length, haven't we?
8	one some range within this.	8	A. Yes.
9	QUESTIONS BY MR. THOMAS:	9	Q. You continue in your opinion,
10	Q. For mesh that is implanted for	10	you say, "It should be mentioned that in the
11	the treatment of stress urinary incontinence,	11	field of abdominal wall hernia repair, the
12	if a force is applied to the mesh, both ends	12	use of large pore, light-weight meshes has
13	of the mesh have the flexibility to move,	13	become a standard recommended by guidelines
14	don't they, with the tissue?	14	and meta-analysis."
15	MR. ANDERSON: Objection to	15	Why is it important to you that
16	form.	16	in the field of abdominal wall hernia repair
17	THE WITNESS: Yes. They have	17	the use of large pore, light-weight meshes
18	the yeah.	18	has become a standard recommended by
19	QUESTIONS BY MR. THOMAS:	19	guidelines and meta-analysis?
20	Q. Okay. In the test method that	20	A. Just to confirm that the fact
21	you and Dr. Mühl devised for the measure of	21	that large pore textile constructions are
22	the uniaxial loading, when you test the force	22	widely accepted in the field of abdominal
23	to measure the effective porosity, one end of	23	wall hernia surgery with all the history, and
24	the mesh can't move, correct?	24	this is not only a fact that is indicated by
	Page 491		Page 493
1	A. Yes. And this leads to the	1	some preclinical animal experiments, but it
2	question what period of implantation of mesh	2	is widely accepted in the world of surgery
3	you want to get this information for.	3	that, yeah.
4	If you're looking for the	4	Q. When you talk about a standard
5	situation where the surgeon applies this	5	recommended by guidelines, to what are you
6	material, he has to have it in his hands. So	6	referring there?
7	he fixed one immediately and that is a	7	A. There are the European Hernia
8	situation that is probably more closer to the	8	Society that has guidelines for the treatment
9	testing.	9	of groin hernia, and they said that it is
10	Of course, there is another	10	advantages to use a large pore, light-weight
11	situation after three months, after one year	11	meshes. There is the International
12	when you have all of this tissue integration	12	Endoscopic Hernia Society that has recently
13	there and so.	13	published guidelines for the treatment of
14	Q. Let's go to page 59 of your	14	endoscopic hernia repair and now for the
15	report, please.	15	treatment of laparoscopic incisional hernia
16	Right in the middle of the page	16	repair under the guidance of Bittner,
17	you're talking about, "The danger of	17	Professor Bittner, and they have a chapter,
18	heavy-weight, small pore hernia mesh and its	18	"Impact and Selection of Mesh Material," and
19	impact on tissue reaction when using the	19	there it is clearly expressed that large pore
20	hernia mesh Prolene® for your gynecological	20	constructions have advantages and should
21	slings," correct?	21	be should be used and in these guidelines,
22	A. Yes.	22	you will find the references to the
23	Q. You say, "It is my opinion to a	23	meta-analysis that has been published some in
24	reasonable degree of medical and scientific	24	Hernia.

39 (Pages 490 to 493)

	Page 494		Page 496
1	I know that there are some	1	(Off the record at 12:27 p.m.)
2	meta-analysis coming to the result	2	(Klinge Exhibit 22 marked for
3	nonsignificant result difference, but more	3	identification.)
4	or less taking these meta-analysis and these	4	QUESTIONS BY MR. THOMAS:
5	guidelines. It is well-accepted in the	5	Q. Doctor, I hand you a document
6	society or in the field of hernia surgeon to	6	that's been marked as Deposition Exhibit
7	use material reduced large pore meshes. It's	7	Number 22.
8	no doubt about it. No yeah.	8	Deposition Exhibit Number 22 is
9	Q. No doubt about it based upon	9	a section from a book called "Hernia Repair
10	the standards you just identified	10	Sequela," written by Volker Schumpelick and
11	A. Not based upon, but this	11	Robert J. Fitzgibbons.
12	these guidelines are reflecting the	12	Is that Professor Schumpelick
13	literature, the opinion of experts, there are	13	the same person that is your superior at your
14	different levels of recommendations. So it's	14	office at the university?
15	not because of the guidelines, but the	15	A. That was?
16	guidelines indicate that this acceptance of	16	Q. Is that the same Schumpelick
17	the surgeons.	17	that you worked for at the university?
18	Q. The meta-analysis studies the	18	A. Yes. Yes.
19	data, correct, and collects the data and	19	Q. And who is Robert Fitzgibbons?
20	draws conclusions from the existing studies?	20	A. He is an American surgeon who
21	A. Yes.	21	is a co-editor for this work and the
22	Q. And the guidelines to which you	22	cochairman for this conference.
23	refer are the guidelines of the professional	23	Both are editors of the Hernia
24	organizations who have experience in hernia	24	Journal still additionally to Marc Miserez
	Page 495		Page 497
1	surgery who are familiar with the literature	1	from Leuven. These three from it.
2	and they publish as a professional	2	Q. And it says it's in
3	organization their opinion as to the proper	3	collaboration with Joachim Conze; is that
4	mesh to use in the hernia application?	4	right?
5	A. I don't know whether I got the	5	A. Yes.
6	point. These are not professional	6	Q. And that's the same Dr. Conze
7	organizations. These are organizations by	7	that you worked with at the Aachen group?
8	surgeons. They have according to the	8	Å. Yes.
9	protocol of the oxford community how to make	9	Q. I'm sure you're familiar with
10		1 0	•
	guidelines. You have to make a reading of	10	this chapter, aren't you?
11	guidelines. You have to make a reading of the literature. You have to classify the	11	this chapter, aren't you? A. Yes.
11 12			A. Yes.
	the literature. You have to classify the	11	A. Yes.
12	the literature. You have to classify the literature according to the level of evidence. You have to add the expert	11 12	A. Yes. Q. If you turn to it's 2010. The third page reads,
12 13	the literature. You have to classify the literature according to the level of	11 12 13	A. Yes. Q. If you turn to it's 2010.
12 13 14	the literature. You have to classify the literature according to the level of evidence. You have to add the expert comments on it. You have to pass it several	11 12 13 14	A. Yes. Q. If you turn to it's 2010. The third page reads, "Alloplastic implants for the treatment of
12 13 14 15	the literature. You have to classify the literature according to the level of evidence. You have to add the expert comments on it. You have to pass it several times around so that everyone can give his comment and finally you have some statements,	11 12 13 14 15	A. Yes. Q. If you turn to it's 2010. The third page reads, "Alloplastic implants for the treatment of stress urinary incontinence and pelvic organ prolapse," shows you as a coauthor with
12 13 14 15 16	the literature. You have to classify the literature according to the level of evidence. You have to add the expert comments on it. You have to pass it several times around so that everyone can give his	11 12 13 14 15 16	A. Yes. Q. If you turn to it's 2010. The third page reads, "Alloplastic implants for the treatment of stress urinary incontinence and pelvic organ
12 13 14 15 16 17	the literature. You have to classify the literature according to the level of evidence. You have to add the expert comments on it. You have to pass it several times around so that everyone can give his comment and finally you have some statements, what are the facts and then you have finally	11 12 13 14 15 16 17	A. Yes. Q. If you turn to it's 2010. The third page reads, "Alloplastic implants for the treatment of stress urinary incontinence and pelvic organ prolapse," shows you as a coauthor with and who are those people?
12 13 14 15 16 17	the literature. You have to classify the literature according to the level of evidence. You have to add the expert comments on it. You have to pass it several times around so that everyone can give his comment and finally you have some statements, what are the facts and then you have finally some recommendations.  And this is not a commercial	11 12 13 14 15 16 17	A. Yes. Q. If you turn to it's 2010. The third page reads, "Alloplastic implants for the treatment of stress urinary incontinence and pelvic organ prolapse," shows you as a coauthor with and who are those people? A. This was B. Schuessler, it's Professor Schuessler from Luzern. He's the
12 13 14 15 16 17 18 19	the literature. You have to classify the literature according to the level of evidence. You have to add the expert comments on it. You have to pass it several times around so that everyone can give his comment and finally you have some statements, what are the facts and then you have finally some recommendations.	11 12 13 14 15 16 17 18	A. Yes. Q. If you turn to it's 2010. The third page reads, "Alloplastic implants for the treatment of stress urinary incontinence and pelvic organ prolapse," shows you as a coauthor with and who are those people? A. This was B. Schuessler, it's
12 13 14 15 16 17 18 19 20	the literature. You have to classify the literature according to the level of evidence. You have to add the expert comments on it. You have to pass it several times around so that everyone can give his comment and finally you have some statements, what are the facts and then you have finally some recommendations.  And this is not a commercial thing that is our this is the enthusiasts	11 12 13 14 15 16 17 18 19 20	A. Yes. Q. If you turn to it's 2010. The third page reads, "Alloplastic implants for the treatment of stress urinary incontinence and pelvic organ prolapse," shows you as a coauthor with and who are those people? A. This was B. Schuessler, it's Professor Schuessler from Luzern. He's the head of the gynecological department there,
12 13 14 15 16 17 18 19 20 21	the literature. You have to classify the literature according to the level of evidence. You have to add the expert comments on it. You have to pass it several times around so that everyone can give his comment and finally you have some statements, what are the facts and then you have finally some recommendations.  And this is not a commercial thing that is our this is the enthusiasts trying to define the best therapy.	11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. If you turn to it's 2010. The third page reads, "Alloplastic implants for the treatment of stress urinary incontinence and pelvic organ prolapse," shows you as a coauthor with and who are those people? A. This was B. Schuessler, it's Professor Schuessler from Luzern. He's the head of the gynecological department there, and he's giving this presentation at the St.

40 (Pages 494 to 497)

the manuscript that should be printed and the content of the presentation of Professor Schuessler.  Did you have any responsibility for the presentation of Professor Schuessler? A. My relationship with Professor Schuessler is that we share a lot of ideas, a lot of knowledge. We prepare together some publications and, therefore, some of his ideas are reflecting our experiences in this in this meaning, yeah, I'm responsible for some of the contents he presented there.  Q. Okay. What responsibility did publications and, therefore, the contents he q. Okay. What responsibility did publication of the preparation of this chapter  Page 498  vaginal erosion of Amid type III mesh use content of the presention of Amid type III mesh use content of the presentation of Professor percentation of Professor percentation of Professor percentation of Professor percentation of Amid type III mesh use content of the presentation of Amid type III mesh use single are rosion of Amid type III mesh use single rosion of Amid type III mesh use single rosion of Amid type III mesh use senting a two-year follow-up, which significantly higher compared to zero percent in a two-year follow-up, which significantly higher compared to zero percent in a two-year follow-up, which significantly higher compared to zero percent in a two-year follow-up, which significantly higher compared to zero percent in a two-year follow-up, which significantly higher compared to zero percent in a two-year follow-up, which significantly higher compared to zero percent in a two-year follow-up, which significantly higher compared to zero percent in a two-year follow-up, which significantly higher compared to zero percent in a two-year follow-up, which significantly higher compared to zero percent in a two-year follow-up, which significantly higher compared to zero percent in a two-year follow-up, which significantly higher compared to zero percent in a two-year follow-up, which significantly higher compared to zero percent in a two-year follow-up, which significantl	s is cent orous same
2 content of the presentation of Professor 3 Schuessler. 4 Q. Did you have any responsibility 5 for the presentation of Professor Schuessler? 6 A. My relationship with Professor 7 Schuessler is that we share a lot of ideas, a 8 lot of knowledge. We prepare together some 9 publications and, therefore, some of his 10 ideas are reflecting our experiences in 11 this in this meaning, yeah, I'm 12 responsible for some of the contents he 13 presented there. 14 Q. Okay. What responsibility did 15 you have for the preparation of this chapter  2 for intravaginal sling plasty was as high a 3 9 percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 6 significantly higher compared to zero percent in a two-year follow-up, which 6 significantly higher compared to zero percent in a two-year follow-up, which 10 significantly higher compared to zero percent in a two-year follow-up, which 10 significantly higher compared to zero percent in a two-year follow-	s is cent orous same
3 Schuessler. 4 Q. Did you have any responsibility 5 for the presentation of Professor Schuessler? 6 A. My relationship with Professor 7 Schuessler is that we share a lot of ideas, a 8 lot of knowledge. We prepare together some 9 publications and, therefore, some of his 10 ideas are reflecting our experiences in 11 this in this meaning, yeah, I'm 12 responsible for some of the contents he 13 presented there. 14 Q. Okay. What responsibility did 15 you have for the preparation of this chapter  3 9 percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, which 4 significantly higher compared to zero percent in a two-year follow-up, the classical TVT®, type 1 macroper in the significantly higher compared to zero percent in a two-year follow-up, the classical TVT®, type 1 macroper in the significantly higher compared to zero percent in a two-year follow-up, the classical TVT®, type 1 macroper in the significantly higher compared to zero percent in the significantly higher compared to zero percent in the significantly higher compared to zero percent in the significant in th	is cent orous same
4 Q. Did you have any responsibility 5 for the presentation of Professor Schuessler? 6 A. My relationship with Professor 7 Schuessler is that we share a lot of ideas, a 8 lot of knowledge. We prepare together some 9 publications and, therefore, some of his 10 ideas are reflecting our experiences in 11 this in this meaning, yeah, I'm 12 responsible for some of the contents he 13 presented there. 14 Q. Okay. What responsibility did 15 you have for the preparation of this chapter  4 significantly higher compared to zero percent in using the classical TVT®, type 1 macroper in monofilament polypropylene mesh in the trial."  8 And that's the Johnson & Johnson mesh, Ethicon?  10 A. I guess I have seen the original publication to this, but it would be misleading to not to mention the first sentence, "Less erosion rates depend on the selection of the material" and, therefore, this study and this article confirms the	cent orous same
for the presentation of Professor Schuessler? A. My relationship with Professor Schuessler is that we share a lot of ideas, a lot of knowledge. We prepare together some publications and, therefore, some of his ideas are reflecting our experiences in this in this meaning, yeah, I'm responsible for some of the contents he presented there.  Q. Okay. What responsibility did you have for the preparation of this chapter  5 using the classical TVT®, type 1 macrope 6 monofilament polypropylene mesh in the 7 trial."  8 And that's the Johnson & 9 Johnson mesh, Ethicon? 10 A. I guess I have seen the 11 original publication to this, but it would b 12 misleading to not to mention the first 13 sentence, "Less erosion rates depend on the selection of the material" and, therefore, 15 this study and this article confirms the	orous same
A. My relationship with Professor  Schuessler is that we share a lot of ideas, a  lot of knowledge. We prepare together some  publications and, therefore, some of his  ideas are reflecting our experiences in  this in this meaning, yeah, I'm  responsible for some of the contents he  presented there.  Q. Okay. What responsibility did  you have for the preparation of this chapter  6 monofilament polypropylene mesh in the  7 trial."  8 And that's the Johnson &  9 Johnson mesh, Ethicon?  10 A. I guess I have seen the  11 original publication to this, but it would b  12 misleading to not to mention the first  13 sentence, "Less erosion rates depend on the selection of the material" and, therefore,  15 this study and this article confirms the	same
7 trial." 8 lot of knowledge. We prepare together some 9 publications and, therefore, some of his 10 ideas are reflecting our experiences in 11 this in this meaning, yeah, I'm 12 responsible for some of the contents he 13 presented there. 14 Q. Okay. What responsibility did 15 you have for the preparation of this chapter  7 trial."  8 And that's the Johnson &  9 Johnson mesh, Ethicon?  10 A. I guess I have seen the  11 original publication to this, but it would b  12 misleading to not to mention the first  13 sentence, "Less erosion rates depend on the selection of the material" and, therefore,  15 this study and this article confirms the	
8 lot of knowledge. We prepare together some 9 publications and, therefore, some of his 10 ideas are reflecting our experiences in 11 this in this meaning, yeah, I'm 12 responsible for some of the contents he 13 presented there. 14 Q. Okay. What responsibility did 15 you have for the preparation of this chapter  8 And that's the Johnson & 9 Johnson mesh, Ethicon? 10 A. I guess I have seen the 11 original publication to this, but it would b 12 misleading to not to mention the first 13 sentence, "Less erosion rates depend on the selection of the material" and, therefore, 15 this study and this article confirms the	e
9 publications and, therefore, some of his 10 ideas are reflecting our experiences in 11 this in this meaning, yeah, I'm 12 responsible for some of the contents he 13 presented there. 14 Q. Okay. What responsibility did 15 you have for the preparation of this chapter  9 Johnson mesh, Ethicon? 10 A. I guess I have seen the 11 original publication to this, but it would be 12 misleading to not to mention the first 13 sentence, "Less erosion rates depend on the selection of the material" and, therefore, 15 this study and this article confirms the	Э
10 ideas are reflecting our experiences in 11 this in this meaning, yeah, I'm 12 responsible for some of the contents he 13 presented there. 14 Q. Okay. What responsibility did 15 you have for the preparation of this chapter  10 A. I guess I have seen the 11 original publication to this, but it would b 12 misleading to not to mention the first 13 sentence, "Less erosion rates depend on the selection of the material" and, therefore, 15 this study and this article confirms the	<u>.</u>
this in this meaning, yeah, I'm responsible for some of the contents he presented there.  Q. Okay. What responsibility did you have for the preparation of this chapter  11 original publication to this, but it would b 12 misleading to not to mention the first 13 sentence, "Less erosion rates depend on tl 14 selection of the material" and, therefore, 15 this study and this article confirms the	e
responsible for some of the contents he presented there.  Q. Okay. What responsibility did you have for the preparation of this chapter  presponsible for some of the contents he presented there.  12 misleading to not to mention the first sentence, "Less erosion rates depend on the selection of the material" and, therefore, this study and this article confirms the	
presented there.  13 sentence, "Less erosion rates depend on the selection of the material" and, therefore, using the selection of the material and, therefore, this study and this article confirms the	<u> </u>
14 Q. Okay. What responsibility did 15 you have for the preparation of this chapter 14 selection of the material" and, therefore, 15 this study and this article confirms the	10
you have for the preparation of this chapter   15 this study and this article confirms the	ic .
16 in this book? 16 finding of this study that there is an impact	·t
17 A. I was asked when they prepared 17 of the material on the clinical outcome an	
18 this manuscript as the basic content of the 18 whether it's 9 or zero percent, 1, the power	
presentation of Professor Schuessler. They  19 presentation of Professor Schuessler. They  19 of this study is not sufficient.	1
20 asked me to revise this manuscript because 20 Q. You stand by the language in	
21 some of these aspects are mainly based on our 21 this exhibit, don't you?	
22 work and our experience and, therefore, I was 22 MR. ANDERSON: Objection.	
23 asked to give my comments and corrections to 23 THE WITNESS: I don't see any	
24 this manuscript. So I'm a coworker there. 24 big conflicts of interest or big	
	age 501
1 Q. If you turn to page 440 of 1 mistakes there.	
2 Exhibit 22, that's a category that says, 2 QUESTIONS BY MR. THOMAS:	
3 "Meshes in Stress Urinary Incontinence." 2 QUESTIONS BY MR. THOMAS. 3 Q. What do you understand "gold	
4 Do you see that? 4 standard" to mean?	
5 A. Yes. 5 A. Gold standard is a difficult	
6 Q. Second paragraph says, "At 6 word. I wouldn't use in the moment to de	ine
7 present, the gold standard in SUI surgery is 7 anything.	inc
8 the suburethral sling, using tension-free 8 (Klinge Exhibit 23 marked for	
9 vaginal tape, (TVT®) or the transobturator 9 identification.)	
tape, (TOT) technique."  10 QUESTIONS BY MR. THOMAS:	
11 Do you agree with that 11 Q. Let me show you what I've	
12 statement? 12 marked as Deposition Exhibit Number 23	
13 A. I wouldn't have chosen it. We 13 Deposition Exhibit Number 23 is	
14 had similar discussion in our field of 14 another study that you've been associated	
15 surgery is there any gold standard, what is a 15 with.	
16 gold standard. I made several presentations 16 You recognize this as the Klink	
about this. Today I wouldn't select the word 17 study we talked about yesterday?	
18 "gold standard," but it is not I don't see 18 A. Uh-huh.	
19 that it is a serious mistake to use it in 19 MR. ANDERSON: Yes?	
20 this context of this article. 20 THE WITNESS: Yes.	
Q. Okay. You see in the last 21 MR. ANDERSON: Thank you.	
22 paragraph of that column, right in the middle 22 QUESTIONS BY MR. THOMAS:	
23 they're talking about "A prospective 23 Q. And this is a comparison of	
randomized control trial by Mechia so that 24 long-term biocompatibility of PVDF and	

41 (Pages 498 to 501)

	Page 502		Page 504
1	polypropylene meshes, correct?	1	A. Yes.
2	A. Yes.	2	Q. And what was the goal of the
3	Q. What role did you have in this	3	study?
4	study?	4	A. The goal of the study was to
5	A. My role in this study was	5	see long-term differences between PVDF and
6	mainly to have a look to the data and to work	6	polypropylene meshes.
7	on the manuscript with the interpretation and	7	Q. And the materials that you used
8	the presentation of this data.	8	for this study were supplied by FEG, correct?
9	Q. And all of the authors on this	9	A. Please let me have a look.
10	study are associated with the universities?	10	Q. It's on the second page under
11	A. That's true.	11	"Mesh Materials."
12	Q. And what specialty or	12	A. Yes.
13	discipline does C.D. Klink have?	13	Q. Do you know whether FEG
14	A. He's a journal he's a	14	provided those materials or you were required
15	surgeon. He's a general surgeon.	15	to purchase them?
16	Q. And Dr. Junge, what discipline	16	A. I don't know.
17	or expertise does Dr. Junge have?	17	Q. All right. And the mesh
18	A. The expertise or the medical	18	materials used in this study strike that.
19	profession, he's a surgeon as well. His	19	One of the things that you also
20	expertise is that he has been working since	20	did in this study was to take scanning
21	1996, '7, I guess, in our group. We made a	21	electron microscope images of the explant,
22	lot of different investigations there so he	22	correct?
23	has a he's very familiar with all of these	23	A. Yes.
24	work what we have done.	24	Q. And on page 294 of Exhibit 23,
	Page 503		Page 505
1	Q. And M. Binnebösel, who is that?	1	down under "Results," it says, "Exemplary
2	A. He's a surgical resident who	2	electron microscopy of explanted samples
3	later on came and mainly he worked in this	3	revealed the signs of surface cracking of the
4	field in the past five, six years.	4	polypropylene samples which were not
5	Q. Who is the next person?	5	detectable on the PVDF samples." And then on
6	A. Dr. Alizai, he's a young	6	the right, there are images of what was found
7	resident. He has not finished his surgical	7	in the study, correct?
8	training education and he's just at the	8	A. Yes.
9	beginning of his career.	9	Q. Dr. Klinge, have you discussed
10	Q. And how about the next person?	10	with FEG the fact that the polypropylene that
11	A. Dr. Otto, he is a surgeon. I	11	they use in their mesh implants displays
12	think he has been he's finished his	12	surface cracks such as are depicted in
13	education as a surgeon. He's working	13	photograph 9 or page 294?
14	scientifically for some years meanwhile and	14	A. We discussed these results,
15	in our group, if you want to say, so he	15	yes.
16	mainly is busy to investigate this visible	16	Q. Did you discuss with FEG any
17	mesh structures.	17	risks that you saw to patients who received
18	Q. And Dr. Neumann?	18	the mesh due to the surface cracking that
19	A. Professor Neumann is the head	19	appears in paragraph or picture A on
20	of the department.	20	page 294?
21	Q. The department of surgery?	21	A. Not specifically.
22	A. Of surgery.	22	Q. Have you discussed with FEG at
23	Q. Took Professor Schumpelick's	23	any time any risks of danger to their
24	position?	24	patients because of surface cracking such as

42 (Pages 502 to 505)

1 that depicted in picture A on page 294 of 2 Exhibit 23? 3 A. We since we started to think 4 of PVDF in 1998, we were working to figure 4 MR. ANDERSON: Who di	
2 Exhibit 23? 3 A. We since we started to think 4 of PVDF in 1998, we were working to figure  2 Q. And who did you tell FEG 3 this increased risk? 4 MR. ANDERSON: Who di	
3 A. We since we started to think 4 of PVDF in 1998, we were working to figure 3 this increased risk? 4 MR. ANDERSON: Who di	about
4 of PVDF in 1998, we were working to figure 4 MR. ANDERSON: Who di	
	d vou
5 out the advantages of PVDF. And, therefore, 5 tell who did you tell FEG?	,
6 the study just to us was a confirmation of 6 QUESTIONS BY MR. THOMAS:	
7 the findings from others and demonstrates the 7 Q. Who did you tell at FEG at	oout
8 advantage of PVDF. I didn't yeah, that's 8 this increased risk from what you ob	
9 it. 9 this photograph on paragraph A on p	
10 Q. Okay. FEG uses polypropylene 10 A. To everyone. I'm sure	1
11 in some of its implants, correct? 11 everyone. All of the all of the peo	onle
12 A. Yes. 12 that are involved in this mesh design	
13 Q. And you've been aware that FEG 13 was it and I've discussed it with them	
14 uses polypropylene in some of its implants 14 Q. Dr. Obolensky?	
15 for some time? 15 A. Yes.	
16 A. Yes. 16 Q. Mr. Mullen?	
17 Q. You've been aware that you 17 A. Yes.	
18 understand from conversations with Clavé and 18 Q. Do you know whether FEC	i has
19 Klosterhalfen and others, that there have 19 ever taken any steps to warn the surg	
20 been reports that surface of some 20 that use their products of any risk from	
21 polypropylene meshes show cracks?  21 degradation strike that.	
22 A. Yes. 22 Do you know whether FEG	has
23 Q. Have you ever discussed with 23 ever taken any steps to warn the doc	
24 FEG any risks to their patients because of 24 use their mesh about any risks from	
Page 507	Page 509
1 these observations of surface cracks? 1 surface cracking that's observed in page 1.	aragraph
2 A. It is I always make it clear 2 A?	aragrapii
3 and Bernd Klosterhalfen made it clear since 3 A. I'm not familiar. I'm not	
4 20 years that using polypropylene in 4 familiar with the legal things, what h	as to
5 comparison to PVDF has an increased risk, 5 do something with warning here and	
6 yes. 6 My relationship to the FEG	
7 Q. Did you tell specifically FEG 7 that we together we're in favor of the	
8 that the surface cracking in these photos 8 and that's it. And they tried together	
9 presented a risk to their patients that 9 me to make more and more devices of	
10 received their mesh? 10 PVDF.	y p
11 A. They know this, yes. 11 Q. You don't want to be associ	iated
12 Q. My question is: Did you tell 12 with a product that creates a risk of h	
13 them that? 13 patients they don't know about, do yo	
14 A. Yes, we yeah. 14 MR. ANDERSON: Objection	
15 Q. And what did you tell them 15 form.	
16 about the risk? 16 THE WITNESS: I didn't	I
17 A. That there is a potential risk 17 understand this question.	I
18 of this surface cracking that sometime it may  18 QUESTIONS BY MR. THOMAS:	I
19 be related to some increased inflammatory 19 Q. You don't want to be associated to be a social some increased inflammatory 19 Q. You don't want to be associated to be a social some increased inflammatory 19 Q. You don't want to be associated to be a social some increased inflammatory 19 Q. You don't want to be associated to be a social some increased inflammatory 19 Q. You don't want to be associated to be a social some increased inflammatory 19 Q. You don't want to be a social so the social	iated
20 reaction, more infections. So we always told 20 with a product that creates a risk of h	
21 what is the consequence of a surface 21 patients they don't know about, do yo	
22 cracking. That is an increase of surface 22 MR. ANDERSON: Objection	
23 with all of the consequences and, therefore, 23 form.	
24 this is an increased risk if you have a 24 THE WITNESS: You have	to in

43 (Pages 506 to 509)

	Page 510		Page 512
1	Germany, you have to inform patients	1	that the risk is so high that you have to
2	about risks with a rate of 1 to	2	stop any use of polypropylene in the moment
3	10,000, so in this area.	3	in all devices for all purposes. And that is
4	In the moment, we have the	4	what I expressed clearly at my presentations
5	information of a surface cracking	5	as well. It is a concern and to my opinion,
6	since some years, five, six, seven	6	there is no doubt that this happens, but it
7	years, and before the time we thought	7	is not enough to forbid the use of
8	it was stable. We believed what they	8	polypropylene in medicine in the moment. But
9	have seen there. So this is a recent	9	maybe it happen. It changes.
10	finding and still today there are a	10	Q. What should FEG do about this
11	lot of there are some people from	11	knowledge and its surgeons and its patients
12	the manufacturers and saying that is	12	that receive this mesh?
13	just an artifact. It's not a real	13	A. I don't have any specific
14	complication. We know there are some	14	information what they are doing as a
15	potential risks by the increase of	15	consequence of this. To my knowledge, the
16	surface by this, but I cannot figure	16	way was to use only PVDF.
17	out what is an exact ratio. I even	17	Q. Okay. But is it fair to
18	don't know what happens after	18	understand that based upon your knowledge of
19	30 years, after 40 years.	19	the information available to you at this
20	Our experience up to now is	20	time, you're unable to determine the extent
21	that within the first two years, three	21	to which there is any clinical significance
22	years, there is no report about a	22	to any surface cracking that may be on this
23	ruptured degradated mesh material	23	polypropylene mesh manufactured by FEG; is
24	leading to a recurrence or to a	24	that fair?
	Page 511		Page 513
1	clinical consequence.	1	MR. ANDERSON: Objection to
2	We have no doubts that it	2	form.
3	happens, meanwhile the consequences	3	THE WITNESS: As I told before,
4	has to be carefully surveyed during	4	I have no doubts that surface cracking
5	the next time.	5	and enhancement of surface leads to a
6	QUESTIONS BY MR. THOMAS:	6	higher risk for complications. That
7	Q. You used the rate of one in	7	is a clear relationship, causal
8	10,000. Do you have enough information	8	relationship, that is proven by all
9	available to you to determine whether the	9	our experience and all of this work.
10	risk to a patient who receives a	10	I cannot give you a figure what
11	polypropylene mesh from FEG creates a risk	11	does this mean to have these
12	greater than one in 10,000 that they will	12	materials, but this should be a
13	suffer adverse consequences because of that	13	starting point. If you decide and
14	mesh?	14	that is my consequence, if you decide
15	A. My current opinion to this	15	to sell polypropylene further on in
16 17	point is that at the moment we don't have	16 17	your devices, you should study it
18	sufficient data to quantify exactly the	18	very, very carefully because this, of
19	consequence of this finding to the clinical	19	course, is not a nonlinear process.
20	outcome. We don't have any doubt, there is no doubt that it happens, that you have this	20	It happens it may happen that 20, 30 years after implantation in young
21	degradation and there is no doubt that in	21	patients that you may experience
22	principle, surface enhancement leads to some	22	things you don't want to see there.
23	complications. But I will not or to my	23	So it has to be studied there.
24	opinion, to my knowledge, it is not like this	24	50 K has to be studied diole.

44 (Pages 510 to 513)

Q. Do you have any ideas as to what you would expect to see? A. In the worst case for the patient, it can be a malignant transformation because you have 30 years of chronic finding mation. We know this from medicine in may cause some malignant transformation, and, this was, of course, the severest Q. Polypropylene sutures have been used now for over 50 years, haven't they? A. Yes. Q. Are you aware of any reports in the literature about clinical issues A. When we're looking to the polypropylene sutures? A. When we're looking to the literature, the number of scientific in youynetisliad is very, very limited and mainly for the meshes with the huge amount of sutures, it would be a better material to be  Page 515  Q. Wy question is not whether you show the surface cracking. My question is whether there are clinical manifestations resulting from the elleged surface cracking? A. I don't know any study that was able to differentiate whether it was a surface of the material, whether it was a surface or cacking, whether it was the functional biocompatibility of the device, therefore.  Q. Last year when you testified, you testified that polypropylene mesh appropriately designed could be used in a mesh.  Do you recall that?  A. Yes.  Go ahead.  QUESTIONS BY MR. THOMAS:  It depends fon — can you please because it depends on — can you please repeat?  Q. Is polypropylene fiber still an paperopriate. Is, it a possible solution not being forbidden by laws? Yes.  Q. As —  MR. ANDERSON: Let him finish.  MR. THOMAS: It thought he was,	
Q. Do you have any ideas as to what you would expect to see? A. In the worst case for the patient, it can be a malignant transformation because you have 30 years of chronic inflammation. We know this from medicine in general. Chronic inflammation over 30 years may cause some malignant transformation, and, this was, of course, the severest complications for the patients, yeah. Q. Polypropylene sutures have been used now for over 50 years, haven't they? A. Yes. Q. Are you aware of any reports in the literature about clinical issues rassociated with alleged surface cracking. My question is whether there are clinical manifestations resulting from the alleged surface cracking? A. I don't know any study that was able to differentiate whether it was a surface of the material, whether it was a surface of the material, whether it was a surface oracking,	
what you would expect to see?  A. In the worst case for the patient, it can be a malignant transformation because you have 30 years of chronic inflammation. We know this from medicine in general. Chronic inflammation over 30 years may cause some malignant transformation, and, this was, of course, the severest complications for the patients, yeah.  Q. Polypropylene sutures have been used now for over 50 years, haven't they?  A. Yes.  Q. Are you aware of any reports in the literature about clinical issues associated with alleged surface cracking; A. Yes.  A. Yes.  MR. ANDERSON: Objection.  Mischaracterizes his testimony.  Go ahead.  QUESTIONS BY MR. THOMAS:  Q. Do you still believe that?  Has your opinion changed?  A. No. Can you, please, because in the field.  Page  investigated these effects with meshes. It mainly started in 1994. So you don't have a knowledge of 50 years of extensive research in this field.  When you if you would asked me five years before whether do you know some  whether there are clinical manifestations resulting from the alleged surface cracking?  A. I don't know any study that was sable to differentiate whether it was a surface of the material, whether it was the functional biocompatibility of the device, therefore.  Q. Last year when you testified, you testified that polypropylene msh appropriately designed could be used in a mesh.  A. Yes.  MR. ANDERSON: Objection.  Mischaracterizes his testimony.  Go ahead.  QUESTIONS BY MR. THOMAS:  Q. Do you still believe that?  Has your opinion changed?  A. No. Can you, please, because it depends on can you please repeat?  Q. Is polypropylene fiber still an  Page  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.  MR. ANDERSON: Let him finish.	
A. In the worst case for the patient, it can be a malignant transformation because you have 30 years of chronic rinflammation. We know this from medicine in general. Chronic inflammation over 30 years may cause some malignant transformation, and, this was, of course, the severest complications for the patients, yeah.  Q. Polypropylene sutures have been used now for over 50 years, haven't they?  A. Yes. Q. Are you aware of any reports in the literature about clinical issues associated with alleged surface cracking in polypropylene sutures?  A. When we're looking to the literature, the number of scientific investigations of tissue response to foreign body materials is very, very limited and amainly for the meshes with the huge amount of sutures, it would be a better material to be  Page 515  When you if you would asked me five years before whether do you know some  A. I don't know any study that was able to differentiate whether it was a surface of the material, whether it was a surface of the material, whether it was the functional biocompatibility of the device, therefore.  Q. Last year when you testified, you testified that polypropylene mesh appropriately designed could be used in a mesh.  Do you recall that?  A. Yes.  MR. ANDERSON: Objection.  Mischaracterizes his testimony.  Go ahead.  QUESTIONS BY MR. THOMAS:  Q. Do you still believe that?  Has your opinion changed?  A. No. Can you, please, because it depends on can you please repeat?  Q. Is polypropylene fiber still an propriate. Is it apossible solution not being forbidden by laws? Yes.  When you if you would asked me five years before whether do you know some	
patient, it can be a malignant transformation because you have 30 years of chronic inflammation. We know this from medicine in general. Chronic inflammation over 30 years may cause some malignant transformation, and, this was, of course, the severest complications for the patients, yeah.  Q. Polypropylene sutures have been used now for over 50 years, haven't they?  A. Yes.  Q. Are you aware of any reports in the literature about clinical issues foliate associated with alleged surface cracking in polypropylene sutures?  A. When we're looking to the literature, the number of scientific investigations of tissue response to foreign body materials is very, very limited and mainly for the meshes with the huge amount of sutures, it would be a better material to be  Page 515  A. I don't know any study that was abule to differentiate whether it was a surface of the material, whether it was a surface of the material, whether it was a surface of the material operations of the material, whether it was a surface of the material, whether it was the functional biocompatibility of the device, therefore.  Q. Last year when you testified, you testified that polypropylene mesh appropriately designed could be used in a mesh.  MR. ANDERSON: Objection.  Mischaracterizes his testimony. Go ahead.  QUESTIONS BY MR. THOMAS: Has your opinion changed? A. No. Can you, please, because it depends on can you please repeat? Q. Is polypropylene fiber still an  Page 515  Page  investigated these effects with meshes. It mainly started in 1994. So you don't have a knowledge of 50 years of extensive research in this field.  When you if you would asked me five years before whether do you know some	
because you have 30 years of chronic inflammation. We know this from medicine in general. Chronic inflammation over 30 years may cause some malignant transformation, and, this was, of course, the severest tomplications for the patients, yeah.  Q. Polypropylene sutures have been used now for over 50 years, haven't they?  A. Yes. Q. Are you aware of any reports in the literature about clinical issues associated with alleged surface cracking in polypropylene sutures?  A. When we're looking to the literature, the number of scientific pody materials is very, very limited and mainly for the meshes with the huge amount of sutures, it would be a better material to be  Page 515 When you if you would asked me five years before whether do you know some  able to differentiate whether it was a surface of the material, whether it was a surface of the material, whether it was a surface cracking, whether it was a surface cracking, whether it was a surface of the material, whether it was the functional biocompatibility of the device, therefore.  Q. Last year when you testified, you testified that polypropylene mesh appropriately designed could be used in a mesh.  Do you recall that?  A. Yes.  MR. ANDERSON: Objection.  Mischaracterizes his testimony.  Go ahead.  QUESTIONS BY MR. THOMAS:  A. No. Can you, please, because it depends on can you please repeat?  Q. Is polypropylene fiber still an paper priate material to be used in a mesh?  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.  MR. ANDERSON: Let him finish.	
inflammation. We know this from medicine in general. Chronic inflammation over 30 years may cause some malignant transformation, and, this was, of course, the severest complications for the patients, yeah.  Q. Polypropylene sutures have been used now for over 50 years, haven't they?  A. Yes.  Q. Are you aware of any reports in the literature about clinical issues associated with alleged surface cracking in polypropylene sutures?  A. When we're looking to the literature, the number of scientific investigations of tissue response to foreign body materials is very, very limited and mainly for the meshes with the huge amount of sutures, it would be a better material to be  Page 515  When you if you would asked me five years before whether do you know some  3 inflammation over 30 years surface of the material, whether it was the functional biocompatibility of the device, therefore.  Q. Last year when you testified, you testified that polypropylene mesh appropriately designed could be used in a mesh.  Do you recall that?  A. Yes.  MR. ANDERSON: Objection.  Mischaracterizes his testimony.  Go ahead.  QUESTIONS BY MR. THOMAS:  Q. Do you still believe that?  Has your opinion changed?  A. No. Can you, please, because it depends on can you please repeat?  Q. Is polypropylene fiber still an  Page 515  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.  MR. ANDERSON: Let him finish.	
general. Chronic inflammation over 30 years may cause some malignant transformation, and, this was, of course, the severest complications for the patients, yeah.  Q. Polypropylene sutures have been used now for over 50 years, haven't they?  A. Yes.  Q. Are you aware of any reports in the literature about clinical issues associated with alleged surface cracking in polypropylene sutures?  A. When we're looking to the literature, the number of scientific investigations of tissue response to foreign body materials is very, very limited and mainly for the meshes with the huge amount of sutures, it would be a better material to be  Page 515  when you recall that?  A. Yes.  MR. ANDERSON: Objection.  Mischaracterizes his testimony.  Go ahead.  QUESTIONS BY MR. THOMAS:  Q. Do you still believe that?  Has your opinion changed?  A. No. Can you, please, because it depends on — can you please repeat?  Q. Is polypropylene fiber still an appropriate. Is it a possible solution not being forbidden by laws? Yes.  MR. ANDERSON: Let him finish.	
may cause some malignant transformation, and, this was, of course, the severest complications for the patients, yeah.  Q. Polypropylene sutures have been used now for over 50 years, haven't they?  A. Yes.  Q. Are you aware of any reports in the literature about clinical issues associated with alleged surface cracking in polypropylene sutures?  A. When we're looking to the literature, the number of scientific investigations of tissue response to foreign body materials is very, very limited and mainly for the meshes with the huge amount of sutures, it would be a better material to be  Page 515  may cause some malignant transformation, and, this was, of course, the severest complications for the severest complications for the severest complications for the patients, yeah.  11	
this was, of course, the severest complications for the patients, yeah.  Q. Polypropylene sutures have been used now for over 50 years, haven't they?  A. Yes.  Q. Are you aware of any reports in the literature about clinical issues associated with alleged surface cracking in polypropylene sutures?  A. When we're looking to the literature, the number of scientific polymaterials is very, very limited and mainly for the meshes with the huge amount of sutures, it would be a better material to be  Page 515  when you if you would asked me five years before whether do you know some  10  Q. Last year when you testified, you testified that polypropylene mesh appropriately designed could be used in a mesh.  Do you recall that?  A. Yes.  MR. ANDERSON: Objection.  Mischaracterizes his testimony.  Go ahead.  QUESTIONS BY MR. THOMAS:  Q. Do you still believe that?  Has your opinion changed?  A. No. Can you, please, because it depends on can you please repeat?  Q. Is polypropylene fiber still an  Page 515  A. Yes.  MR. ANDERSON: Objection.  Mischaracterizes his testimony.  Go ahead.  QUESTIONS BY MR. THOMAS:  A. No. Can you, please, because it depends on can you please repeat?  Q. Is polypropylene fiber still an  Page 515  A. Yes.  A. Yes.  MR. ANDERSON: Objection.  Mischaracterizes his testimony.  Go ahead.  QUESTIONS BY MR. THOMAS:  A. No. Can you, please, because it depends on can you please repeat?  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.  Q. As  MR. ANDERSON: Let him finish.	
complications for the patients, yeah.  Q. Polypropylene sutures have been used now for over 50 years, haven't they?  A. Yes.  Q. Are you aware of any reports in the literature about clinical issues the literature about clinical issues 16 MR. ANDERSON: Objection.  Mischaracterizes his testimony.  Go ahead.  QUESTIONS BY MR. THOMAS:  Literature, the number of scientific 20 Q. Do you still believe that?  Investigations of tissue response to foreign 21 investigated these effects with meshes. It 22 mainly started in 1994. So you don't have a 3 knowledge of 50 years of extensive research in this field.  When you if you would asked 6 me five years before whether do you know some  11 you testified that polypropylene mesh appropriately designed could be used in a mesh.  22 appropriately designed could be used in a mesh.  Do you recall that?  A. Yes.  MR. ANDERSON: Objection.  Mischaracterizes his testimony.  Go ahead.  QUESTIONS BY MR. THOMAS:  Q. Do you still believe that?  Has your opinion changed?  A. No. Can you, please, because it depends on can you please repeat?  Q. Is polypropylene fiber still an  Page 515  Page  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.  Q. As  MR. ANDERSON: Let him finish.	
12 Q. Polypropylene sutures have been 13 used now for over 50 years, haven't they? 14 A. Yes. 15 Q. Are you aware of any reports in 16 the literature about clinical issues 16 MR. ANDERSON: Objection. 17 associated with alleged surface cracking in 18 polypropylene sutures? 19 A. When we're looking to the 20 literature, the number of scientific 21 investigations of tissue response to foreign 22 body materials is very, very limited and 23 mainly for the meshes with the huge amount of 24 sutures, it would be a better material to be 25 mainly started in 1994. So you don't have a 26 knowledge of 50 years of extensive research 27 in this field. 28 polypropylene sutures in a mesh. 29	
13 used now for over 50 years, haven't they?  14 A. Yes.  15 Q. Are you aware of any reports in  16 the literature about clinical issues  16 MR. ANDERSON: Objection.  17 associated with alleged surface cracking in  18 polypropylene sutures?  19 A. When we're looking to the  20 literature, the number of scientific  21 investigations of tissue response to foreign  22 body materials is very, very limited and  23 mainly for the meshes with the huge amount of  24 sutures, it would be a better material to be  25 mainly started in 1994. So you don't have a  3 knowledge of 50 years of extensive research  4 in this field.  5 When you if you would asked  6 me five years before whether do you know some  13 mesh.  14 Do you recall that?  A. Yes.  15 A. Yes.  MR. ANDERSON: Objection.  Mischaracterizes his testimony.  Go ahead.  QUESTIONS BY MR. THOMAS:  19 Has your opinion changed?  A. No. Can you, please, because it depends on can you please repeat?  Q. Is polypropylene fiber still an  Page 515  A. Yes.  MR. ANDERSON: Let him finish.	
14 A. Yes. 15 Q. Are you aware of any reports in 16 the literature about clinical issues 17 associated with alleged surface cracking in 18 polypropylene sutures? 19 A. When we're looking to the 20 literature, the number of scientific 21 investigations of tissue response to foreign 22 body materials is very, very limited and 23 mainly for the meshes with the huge amount of 24 sutures, it would be a better material to be  Page 515  1 investigated these effects with meshes. It 2 mainly started in 1994. So you don't have a 3 knowledge of 50 years of extensive research 4 in this field. 5 When you if you would asked 6 me five years before whether do you know some  16 MR. ANDERSON: Objection. 17 Mischaracterizes his testimony. 18 Go ahead. 20 QUESTIONS BY MR. THOMAS: 20 Q. Do you still believe that? 21 Has your opinion changed? 22 A. No. Can you, please, because it depends on can you please repeat? 23 it depends on can you please repeat? 24 Q. Is polypropylene fiber still an  Page 515  A. Yes.  A. Yes.  A. Ves.  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.  Q. As  MR. ANDERSON: Let him finish.	
15 Q. Are you aware of any reports in 16 the literature about clinical issues 17 associated with alleged surface cracking in 18 polypropylene sutures? 19 A. When we're looking to the 20 literature, the number of scientific 21 investigations of tissue response to foreign 22 body materials is very, very limited and 23 mainly for the meshes with the huge amount of 24 sutures, it would be a better material to be 19 QUESTIONS BY MR. THOMAS: 20 Q. Do you still believe that? 21 Has your opinion changed? 22 A. No. Can you, please, because 23 it depends on can you please repeat? 24 sutures, it would be a better material to be 25 page 515 26 Investigated these effects with meshes. It 27 mainly started in 1994. So you don't have a 28 knowledge of 50 years of extensive research 4 in this field. 5 When you if you would asked 6 me five years before whether do you know some 20 Lis polypropylene fiber still an papropriate. Is it a possible solution not being forbidden by laws? Yes. 29 Lis polypropylene fiber still an papropriate. Is it a possible solution not being forbidden by laws? Yes. 20 Lis polypropylene fiber still an papropriate. Is it a possible solution not being forbidden by laws? Yes. 21 has your opinion changed? 22 A. No. Can you, please, because it depends on can you please repeat? 23 appropriate material to be used in a mesh? 24 A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes. 25 Q. As 26 MR. ANDERSON: Let him finish.	
the literature about clinical issues  16 MR. ANDERSON: Objection.  17 Associated with alleged surface cracking in  18 polypropylene sutures?  19 A. When we're looking to the  20 literature, the number of scientific  21 investigations of tissue response to foreign  22 body materials is very, very limited and  23 mainly for the meshes with the huge amount of  24 sutures, it would be a better material to be  Page 515  1 investigated these effects with meshes. It  2 mainly started in 1994. So you don't have a  3 knowledge of 50 years of extensive research  4 in this field.  5 When you if you would asked  6 me five years before whether do you know some  16 MR. ANDERSON: Objection.  17 Mischaracterizes his testimony.  18 Go ahead.  19 QUESTIONS BY MR. THOMAS:  20 Q. Do you still believe that?  21 Has your opinion changed?  22 A. No. Can you, please, because it depends on can you please repeat?  23 it depends on can you please repeat?  Q. Is polypropylene fiber still an  Page 515  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.  Q. As  MR. ANDERSON: Let him finish.	
17 associated with alleged surface cracking in 18 polypropylene sutures? 19 A. When we're looking to the 20 literature, the number of scientific 21 investigations of tissue response to foreign 22 body materials is very, very limited and 23 mainly for the meshes with the huge amount of 24 sutures, it would be a better material to be  Page 515  1 investigated these effects with meshes. It 2 mainly started in 1994. So you don't have a 3 knowledge of 50 years of extensive research 4 in this field. 5 When you if you would asked 6 me five years before whether do you know some  Page 515  Mischaracterizes his testimony.  Go ahead.  19 QUESTIONS BY MR. THOMAS:  20 Q. Do you still believe that?  A. No. Can you, please, because it depends on can you please repeat?  Q. Is polypropylene fiber still an  Page 515  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.  Q. As  MR. ANDERSON: Let him finish.	
18 polypropylene sutures? 19 A. When we're looking to the 20 literature, the number of scientific 21 investigations of tissue response to foreign 22 body materials is very, very limited and 23 mainly for the meshes with the huge amount of 24 sutures, it would be a better material to be  Page 515  1 investigated these effects with meshes. It 2 mainly started in 1994. So you don't have a 3 knowledge of 50 years of extensive research 4 in this field. 5 When you if you would asked 6 me five years before whether do you know some  18 Go ahead. 19 QUESTIONS BY MR. THOMAS: 20 Q. Do you still believe that? 4 Has your opinion changed? 21 A. No. Can you, please, because it depends on can you please repeat? Q. Is polypropylene fiber still an  Page 515  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes. Q. As MR. ANDERSON: Let him finish.	
A. When we're looking to the literature, the number of scientific 20 literature, the number of scientific 21 investigations of tissue response to foreign 21 has your opinion changed? 22 hody materials is very, very limited and 23 mainly for the meshes with the huge amount of 24 sutures, it would be a better material to be 24 sutures, it would be a better material to be 25 literature, it would be a better material to be 26 literature, it would be a better material to be 27 literature, it would be a better material to be 28 literature, it would be a better material to be 29 literature, it depends on can you please repeat? 29 literature, it depends on can you please repeat? 20 literature, it depends on can you please repeat? 21 literature, it depends on can you please repeat? 22 literature, it depends on can you please repeat? 23 literature, it depends on can you please repeat? 24 literature, it depends on can you please repeat? 25 literature, it depends on can you please repeat? 26 literature, it depends on can you please repeat? 27 literature, it depends on can you please repeat? 28 literature, it depends on can you please repeat? 29 literature, it depends on can you please repeat? 29 literature, it depends on can you please repeat? 20 literature, it depends on can you please repeat? 20 literature, it depends on can you please repeat? 20 literature, it depends on can you please repeat? 20 literature, it depends on can you please repeat? 21 literature, it depends on can you please repeat? 22 literature, it depends on can you please repeat? 23 literature, it depends on can you please repeat? 24 literature, it depends on can you please repeat? 24 literature, it depends on can you please repeat? 24 literature, it depends on can you please repeat? 24 literature, it depends on can you please repeat? 24 literature, it depends on can you please repeat? 24 literature, it depends on can you please repeat? 24 literature, it depends on can you	
20 literature, the number of scientific 21 investigations of tissue response to foreign 22 body materials is very, very limited and 23 mainly for the meshes with the huge amount of 24 sutures, it would be a better material to be  Page 515  1 investigated these effects with meshes. It 2 mainly started in 1994. So you don't have a 3 knowledge of 50 years of extensive research 4 in this field. 5 When you if you would asked 6 me five years before whether do you know some  20 Q. Do you still believe that?  Has your opinion changed?  A. No. Can you, please, because it depends on can you please repeat?  Q. Is polypropylene fiber still an  Page 515  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.  Q. As  MR. ANDERSON: Let him finish.	
21 investigations of tissue response to foreign 22 body materials is very, very limited and 23 mainly for the meshes with the huge amount of 24 sutures, it would be a better material to be  Page 515  Page 515  I investigated these effects with meshes. It 2 mainly started in 1994. So you don't have a 3 knowledge of 50 years of extensive research 4 in this field.  When you if you would asked 5 When you if you would asked 6 me five years before whether do you know some  Page 515  Has your opinion changed?  A. No. Can you, please, because it depends on can you please repeat?  Q. Is polypropylene fiber still an  Page 515  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.  Q. As  MR. ANDERSON: Let him finish.	
body materials is very, very limited and mainly for the meshes with the huge amount of sutures, it would be a better material to be  Page 515  Investigated these effects with meshes. It mainly started in 1994. So you don't have a sknowledge of 50 years of extensive research in this field.  When you if you would asked form the meshes with the huge amount of the page it depends on can you please repeat?  A. No. Can you, please, because it depends on can you please repeat?  A. No. Can you, please, because it depends on can you please repeat?  A. Is polypropylene fiber still an page 515  Page 515  A. No. Can you, please, because it depends on can you please repeat?  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.  When you if you would asked 5 Q. As MR. ANDERSON: Let him finish.	
mainly for the meshes with the huge amount of sutures, it would be a better material to be  Page 515  Investigated these effects with meshes. It mainly started in 1994. So you don't have a sknowledge of 50 years of extensive research in this field.  When you if you would asked feeling for better the five years before whether do you know some it depends on can you please repeat?  Q. Is polypropylene fiber still an page 515  Page 515  A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.  Q. As  MR. ANDERSON: Let him finish.	
sutures, it would be a better material to be  Page 515  Page 515  Investigated these effects with meshes. It appropriate material to be used in a mesh?  mainly started in 1994. So you don't have a sknowledge of 50 years of extensive research in this field.  When you if you would asked to me five years before whether do you know some to me five years before whether do you know some to the page 515  Page 515  A. It depends from your meaning of appropriate. Is it a possible solution not to being forbidden by laws? Yes.  Q. As  MR. ANDERSON: Let him finish.	
Page 515  Page 515  Investigated these effects with meshes. It mainly started in 1994. So you don't have a knowledge of 50 years of extensive research in this field.  When you if you would asked me five years before whether do you know some  Page 515  A appropriate material to be used in a mesh? A appropriate. Is it a possible solution not being forbidden by laws? Yes.  Q As MR ANDERSON: Let him finish.	
1 investigated these effects with meshes. It 2 mainly started in 1994. So you don't have a 3 knowledge of 50 years of extensive research 4 in this field. 5 When you if you would asked 6 me five years before whether do you know some 1 appropriate material to be used in a mesh? 2 A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes. 5 Q. As 6 MR. ANDERSON: Let him finish.	-
2 mainly started in 1994. So you don't have a 3 knowledge of 50 years of extensive research 4 in this field. 5 When you if you would asked 6 me five years before whether do you know some 2 A. It depends from your meaning of 3 appropriate. Is it a possible solution not 4 being forbidden by laws? Yes. 5 Q. As 6 MR. ANDERSON: Let him finish.	517
<ul> <li>knowledge of 50 years of extensive research</li> <li>in this field.</li> <li>When you if you would asked</li> <li>me five years before whether do you know some</li> <li>appropriate. Is it a possible solution not</li> <li>being forbidden by laws? Yes.</li> <li>Q. As</li> <li>MR. ANDERSON: Let him finish.</li> </ul>	
4 in this field. 5 When you if you would asked 6 me five years before whether do you know some 4 being forbidden by laws? Yes. 5 Q. As 6 MR. ANDERSON: Let him finish.	
5 When you if you would asked 5 Q. As 6 me five years before whether do you know some 6 MR. ANDERSON: Let him finish.	
6 me five years before whether do you know some 6 MR. ANDERSON: Let him finish.	
7 cancer case in relationship to textiles, I 7 MR. THOMAS: I thought he was,	
8 would say, no, I don't know any report, but 8 I'm sorry.	
9 meanwhile it changed. Meanwhile we know 9 MR. ANDERSON: He's still	
10 some. 10 counting on his fingers.	
I don't want to say that we 11 THE WITNESS: When I would	
12 have to expect it in certain number of 12 prefer the best material, I wouldn't	
patients, but it is a concern, yes. 13 choose polypropylene.	
14 Q. Are you aware of any reports in 14 QUESTIONS BY MR. THOMAS:	
15 the literature about clinical issues 15 Q. Is PVDF more expensive than	
16 associated with alleged surface cracking in 16 polypropylene?	
polypropylene sutures? 17 Å. It's definitely more expensive,	
A. Polypropylene suture surface 18 and it's more difficult to handle.	T I
19 cracking, there has been reports. I guess La 19 Q. And how much more expensive is	- 1
20 Roche was an investigation of polypropylene 20 it than polypropylene?	
21 sutures in the eyes showing this cracking or 21 A. I don't know.	
22 degradation of this material. So there is 22 Q. When you say it's more	
some literature showing that indicating that 23 difficult to handle, what do you mean?	
24 you have this degradation. 24 A. What I was told by the textile	

45 (Pages 514 to 517)

	Page 518		Page 520
1	engineers since over the past 15 years, you	1	gets to the mesh will make the mesh softer
2	need a specific knowledge of how to make PVDF	2	and more pliable?
3	fibers because you need higher temperature to	3	A. I never realized this in the
4	do so, you need specific equipment, you need	4	context with the with polypropylene or
5	other other spinning equipment to do so.	5	with meshes.
6	Yeah. The advantage is that you can use a	6	We used the pre-coating with
7	pure material.	7	vascular grafts. They were preclotted with
8	Q. Dr. Klinge when a mesh is	8	some substances to change the appearance, but
9	implanted, what bodily fluids surround the	9	for textiles meshes made of polypropylene
10	mesh.	10	with a fiber of in a diameter of
11	A. Immediately when you place it	11	120 microns, I cannot believe that any
12	there, depending on the skill of the surgeon,	12	protein can change significantly the
13	some blood. Usually some blood.	13	properties of this.
14	Q. Do proteins ultimately surround	14	Q. Have you ever studied the
15	the mesh?	15	extent to which bodily fluids soften meshes
16	A. Yes, of course. There are some	16	and make them more pliable?
17	body liquids from the extra cellular liquids	17	A. No.
18	and they contain thousands, hundred thousands	18	Q. When a mesh is explanted, the
19	of proteins and due to the trauma, to the	19	bodily fluids and proteins remain on the
20	stress by the implant, you have a	20	mesh, correct?
21	accumulation of liquid in this area. If you	21	MR. ANDERSON: Objection.
22 23	look very carefully to this area, you always	22 23	THE WITNESS: When you explant
24	find some accumulation of liquid around a textile implant.	24	a mesh, you usually have a block and you have a lot of scar tissue and
24	-	24	
	Page 519		Page 521
1	Q. Is it true that proteins	1	somewhere in between there are these
2	surround the mesh fibers?	2	fibers. There is some liquids, some
3	A. Our current thought is that the	3	cells there, yeah.
4	liquid containing the proteins, they are	4	QUESTIONS BY MR. THOMAS:
5	around the mesh fibers. The proteins	5	Q. And once you take the explant
6	themselves are too small. They just adhere	6	out, you place it into formalin?
7	to the surface, but they are not able to coat	7	A. Yes. Either you want to make
8	the entire filament to my	8	some specific analysis. If you want to make
9	Q. Okay. Do you know of any	9	an electron microscopy, you need some other
10 11	impact or effect that these fluids have on the characteristics of the mesh?	10 11	solution for fixation, or if you want to make some genetic analysis, you have to freeze it
12	MR. ANDERSON: Are you talking	12	down later on making some other so these
13	polypropylene?	13	are the three options you have usually.
14	MR. THOMAS: Yes,	14	Q. Okay. So you can freeze it,
15	polypropylene. Thank you.	15	you can use formalin or
16	THE WITNESS: It is necessary	16	A. Yeah.
17	to think or to specify which	17	Q there's some other
18	characteristic of the mesh.	18	preparation you use for electron microscopy?
19	QUESTIONS BY MR. THOMAS:	19	A. Yes.
20	Q. Have you ever heard of a term	20	Q. Tell me what that is.
21	"plasticizer"?	21	A. For example, glutaraldehyde.
22	A. Yes, but not in the context	22	Q. I'm sorry?
23	with meshes and proteins.	23	A. Glutaraldehyde.
24	Q. That the bodily fluids as it	24	Q. I don't have any idea what you

46 (Pages 518 to 521)

	Page 522		Page 524
1	just said.	1	microscopy where you analyze the extent to
2	MR. ANDERSON: Glutaraldehyde.	2	which there were
3	Or glutaraldehyde.	3	A. Degradation?
4	QUESTIONS BY MR. THOMAS:	4	Q surface cracking found on
5	Q. Okay. Under what circumstances	5	polypropylene?
6	have you used	6	A. Not that I recall.
7	MR. ANDERSON: Glutaraldehyde.	7	Q. Doctor, on pages 40 to 42 of
8	QUESTIONS BY MR. THOMAS:	8	your report, you have three images that come
9	Q glutaraldehyde in the	9	from the report of Dr. Jordi; is that
10	preparation of samples for scanning electron	10	correct?
11	microscopy?	11	A. Yes.
12	A. There has been some time where	12	Q. Did you select the images that
13	we tried in some research projects to do some	13	were to be included in your report?
14	electron microscopy and, therefore, we had to	14	MR. ANDERSON: Objection as to
15	make this specific fixation where we wanted	15	whether or not there's work product
16	to look to the collagen fibers. Collagen 3	16	and who selected what images.
17	has very small fibers. So when we were bound	17	QUESTIONS BY MR. THOMAS:
18	to make this fixation and we were asked to	18	Q. Well, then I'll ask it this
19	make this fixation with glutaraldehyde.	19	way.
20	Q. Why did you use glutaraldehyde	20	Are Figures 13, 14 and 15 of
21	as opposed to formalin or formaldehyde, what	21	any particular significance to you in your
22	was the reason?	22	opinions other than just a representation of
23	A. Because we received a protocol	23	what was seen in images from Dr. Jordi?
24	from the guys making the electron microscopy	24	A. I don't see any significant
	Page 523		Page 525
1	and that we should use this. I'm not an	1	differences to many others so
2	expert to say the different possibilities to	2	Q. Do Figures 13, 14 and 15, to
3	make a preparation for some investigation. I	3	your knowledge, have any relationship to
4	just told you what my experience was that we	4	Carolyn Lewis?
5	have some different options to make it.	5	A. Yes. I know
6	Q. Okay. And how many occasions	6	Q. I didn't see it in your report.
7	have you prepared slides for scanning	7	That's why I'm asking.
8	electron microscopy where you've used	8	A. I remember I received a lot of
9	glutaraldehyde?	9	images from other devices, but from this
10	A. How many slides for electron	10	device specifically as well. I guess it is
11	microscopy?	11	from this case.
12	Q. Yes.	12	Q. How do you know that? You say
13	A. I don't recall. Most often I	13	I guess.
14	think it was to analyze the collagen, the	14	A. I have to be look careful
15	quality of collagens. There we had over	15	every sentence there whether we have already
16	some years, we had projects where we made	16	written it here. Otherwise, if it's not
17	electron microscopy to look to the protein	17	written here, I have to check the files
18	to the collagens.	18	Q. Okay.
19	Q. Have you prepared any samples	19	A with the images there.
		20	Q. I did not find it in your
20	for scanning electron microscopy in the last	l .	· •
21	three years using glutaraldehyde?	21	report where you identified these
21 22	three years using glutaraldehyde?  A. Not that I recall.	21 22	report where you identified these A. Sorry.
21	three years using glutaraldehyde?	21	report where you identified these

47 (Pages 522 to 525)

	Page 526		Page 528
1	the question.	1	Have you studied how
2	MR. ANDERSON: No, but he	2	polypropylene degrades?
3	reviewed Jordi's report.	3	MR. ANDERSON: Objection. It
4	MR. THOMAS: I understand that.	4	was asked yesterday because you wanted
5	And Jordi has 22 mesh explants, too.	5	to get into expert opinions yesterday.
6	I don't know which ones he picked.	6	So we're going back over the same
7	MR. ANDERSON: Yeah, they're	7	ground.
8	all identified by identifying number	8	MR. THOMAS: Not really. I
9	in Jordi's report. So if you want us	9	just didn't remember I asked the
10	to go get Jordi's report out and look	10	question.
11	through and identify which ones are	11	MR. ANDERSON: You asked a lot
12	Ms. Lewis, we can certainly take the	12	of questions on degradation yesterday.
13	time to do that. Or I can tell you	13	MR. THOMAS: Okay.
14	which one it is or however you want to	14	MR. ANDERSON: Because you
15	do it.	15	asked to go ahead and start asking
16	MR. THOMAS: I was going to	16	expert questions yesterday.
17	ask I do want to see the report he	17	MR. THOMAS: Can we keep going
18	has because the report he has is dated	18	so we can get out of here?
19	a different date than the report that	19	QUESTIONS BY MR. THOMAS:
20	you produced. The report that's	20	Q. Can you answer the question?
21	identified in his report is dated	21	MR. ANDERSON: Have you studied
22	October the 12th, 2013.	22	how polypropylene degrades? That's
23	So do you have that with you,	23	his question.
24	the one that he reviewed here?	24	THE WITNESS: We have studying
21	Page 527	21	Page 529
1	MR. ANDERSON: No, but it would	1	in the meaning that looking to the
2	be the exact same report as Jordi did.	2	data, yes. Doing own studies,
3	MR. THOMAS: I don't it's	3	experimental studies looking to the
4	19 days before his deposition. You	4	chemistry, what happens there, no.
5	remember we had two marked there with	5	QUESTIONS BY MR. THOMAS:
6	different dates. I never did figure		
		16	
7	•	6	Q. Do you defer to Dr. Jordi for
7	out	7	Q. Do you defer to Dr. Jordi for that type of analysis?
8	out MR. ANDERSON: Because we	7 8	Q. Do you defer to Dr. Jordi for that type of analysis? A. Yes. Definitely.
8 9	out MR. ANDERSON: Because we reprinted off the first page, and when	7 8 9	<ul><li>Q. Do you defer to Dr. Jordi for that type of analysis?</li><li>A. Yes. Definitely.</li><li>Q. Doctor, let's go to page 76 of</li></ul>
8 9 10	out MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for	7 8 9 10	Q. Do you defer to Dr. Jordi for that type of analysis? A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report
8 9 10 11	out MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as	7 8 9 10 11	Q. Do you defer to Dr. Jordi for that type of analysis? A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."
8 9 10 11 12	out MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.	7 8 9 10 11 12	Q. Do you defer to Dr. Jordi for that type of analysis? A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."  Is it your opinion that
8 9 10 11 12 13	out MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.  QUESTIONS BY MR. THOMAS:	7 8 9 10 11 12 13	Q. Do you defer to Dr. Jordi for that type of analysis?  A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."  Is it your opinion that  ULTRAPRO <sup>TM</sup> is an appropriate alternative
8 9 10 11 12 13	out MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.  QUESTIONS BY MR. THOMAS: Q. As you sit here today, Doctor,	7 8 9 10 11 12 13	Q. Do you defer to Dr. Jordi for that type of analysis?  A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."  Is it your opinion that  ULTRAPRO <sup>TM</sup> is an appropriate alternative design for the treatment of stress urinary
8 9 10 11 12 13 14	out MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.  QUESTIONS BY MR. THOMAS: Q. As you sit here today, Doctor, do you know whether the Figures 13, 14 and 15	7 8 9 10 11 12 13 14	Q. Do you defer to Dr. Jordi for that type of analysis?  A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."  Is it your opinion that  ULTRAPRO <sup>TM</sup> is an appropriate alternative design for the treatment of stress urinary incontinence in women?
8 9 10 11 12 13 14 15	out  MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.  QUESTIONS BY MR. THOMAS:  Q. As you sit here today, Doctor, do you know whether the Figures 13, 14 and 15 are from mesh explanted from Carolyn Lewis?	7 8 9 10 11 12 13 14 15	Q. Do you defer to Dr. Jordi for that type of analysis?  A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."  Is it your opinion that  ULTRAPRO <sup>TM</sup> is an appropriate alternative design for the treatment of stress urinary incontinence in women?  A. No.
8 9 10 11 12 13 14 15 16 17	out MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.  QUESTIONS BY MR. THOMAS: Q. As you sit here today, Doctor, do you know whether the Figures 13, 14 and 15 are from mesh explanted from Carolyn Lewis? A. I'm not sure whether this is	7 8 9 10 11 12 13 14 15 16 17	Q. Do you defer to Dr. Jordi for that type of analysis?  A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."  Is it your opinion that  ULTRAPRO <sup>TM</sup> is an appropriate alternative design for the treatment of stress urinary incontinence in women?  A. No. Q. Why?
8 9 10 11 12 13 14 15 16 17 18	out  MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.  QUESTIONS BY MR. THOMAS:  Q. As you sit here today, Doctor, do you know whether the Figures 13, 14 and 15 are from mesh explanted from Carolyn Lewis?  A. I'm not sure whether this is precisely from her, but they all look quite	7 8 9 10 11 12 13 14 15 16 17	Q. Do you defer to Dr. Jordi for that type of analysis?  A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."  Is it your opinion that  ULTRAPRO <sup>TM</sup> is an appropriate alternative design for the treatment of stress urinary incontinence in women?  A. No. Q. Why? A. Because the structural
8 9 10 11 12 13 14 15 16 17 18 19	out  MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.  QUESTIONS BY MR. THOMAS:  Q. As you sit here today, Doctor, do you know whether the Figures 13, 14 and 15 are from mesh explanted from Carolyn Lewis?  A. I'm not sure whether this is precisely from her, but they all look quite similar.	7 8 9 10 11 12 13 14 15 16 17 18	Q. Do you defer to Dr. Jordi for that type of analysis?  A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."  Is it your opinion that  ULTRAPRO <sup>TM</sup> is an appropriate alternative design for the treatment of stress urinary incontinence in women?  A. No. Q. Why? A. Because the structural stability of ULTRAPRO <sup>TM</sup> is not sufficient to
8 9 10 11 12 13 14 15 16 17 18 19 20	out  MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.  QUESTIONS BY MR. THOMAS:  Q. As you sit here today, Doctor, do you know whether the Figures 13, 14 and 15 are from mesh explanted from Carolyn Lewis?  A. I'm not sure whether this is precisely from her, but they all look quite similar.  Q. Okay. You've told me before	7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Do you defer to Dr. Jordi for that type of analysis?  A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."  Is it your opinion that  ULTRAPRO <sup>TM</sup> is an appropriate alternative design for the treatment of stress urinary incontinence in women?  A. No. Q. Why? A. Because the structural stability of ULTRAPRO <sup>TM</sup> is not sufficient to withstand or to preserve the big pores
8 9 10 11 12 13 14 15 16 17 18 19 20 21	out  MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.  QUESTIONS BY MR. THOMAS:  Q. As you sit here today, Doctor, do you know whether the Figures 13, 14 and 15 are from mesh explanted from Carolyn Lewis?  A. I'm not sure whether this is precisely from her, but they all look quite similar.  Q. Okay. You've told me before that you're not a chemist or an analytical	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Do you defer to Dr. Jordi for that type of analysis?  A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."  Is it your opinion that  ULTRAPRO <sup>TM</sup> is an appropriate alternative design for the treatment of stress urinary incontinence in women?  A. No. Q. Why? A. Because the structural stability of ULTRAPRO <sup>TM</sup> is not sufficient to withstand or to preserve the big pores under under these conditions of
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	out  MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.  QUESTIONS BY MR. THOMAS:  Q. As you sit here today, Doctor, do you know whether the Figures 13, 14 and 15 are from mesh explanted from Carolyn Lewis?  A. I'm not sure whether this is precisely from her, but they all look quite similar.  Q. Okay. You've told me before that you're not a chemist or an analytical chemist.	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Do you defer to Dr. Jordi for that type of analysis?  A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."  Is it your opinion that  ULTRAPRO <sup>TM</sup> is an appropriate alternative design for the treatment of stress urinary incontinence in women?  A. No. Q. Why? A. Because the structural stability of ULTRAPRO <sup>TM</sup> is not sufficient to withstand or to preserve the big pores under under these conditions of biomechanics as it is required for the use as
8 9 10 11 12 13 14 15 16 17 18 19 20 21	out  MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.  QUESTIONS BY MR. THOMAS:  Q. As you sit here today, Doctor, do you know whether the Figures 13, 14 and 15 are from mesh explanted from Carolyn Lewis?  A. I'm not sure whether this is precisely from her, but they all look quite similar.  Q. Okay. You've told me before that you're not a chemist or an analytical	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Do you defer to Dr. Jordi for that type of analysis?  A. Yes. Definitely. Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."  Is it your opinion that  ULTRAPRO <sup>TM</sup> is an appropriate alternative design for the treatment of stress urinary incontinence in women?  A. No. Q. Why? A. Because the structural stability of ULTRAPRO <sup>TM</sup> is not sufficient to withstand or to preserve the big pores under under these conditions of

48 (Pages 526 to 529)

	Page 530		Page 532
1	currently marketed by Ethicon that is an	1	parallel. If you want to have a good
2	appropriate alternative design for the	2	schedule for how to do so, a good example
3	treatment of stress urinary incontinence?	3	of a good realization of this principle is
4	A. I'm not aware of all products	4	what we have done with the VYPRO or the
5	from Ethicon that are available in the	5	principles that we defined at that time, all
6	moment. In this context, I cannot say	6	of these studies, the 100 publications, all
7	whether there is already some device that I	7	of this together gives a good impression or
8	can consider sufficiently to be sufficient.	8	helps you to understand, to find a good
9	It should have it has to be tested all	9	device.
10	these.	10	Q. And you began with the design
11	Q. And when you mean it has to be	11	of VYPRO in 1994?
12	tested, what do you mean?	12	A. 1994.
13	A. To find the optimum structure,	13	As I told you, December
14	the optimum the development for the	14	of 1993.
15	development of the optimum structure, you	15	Q. And when was VYPRO launched?
16	need some studies to define this.	16	A. 1998.
17	Q. Tell me what studies you need.	17	Q. Is it your opinion today that
18	A. More or less you need studies	18	PVDF is the only appropriate polymer to be
19	to every point of concern that was mentioned	19	used in mesh for implantation in the
20	in this report and this these studies to	20	treatment of stress urinary incontinence?
21	every point mentioned in this report	21	A. No, but, to my knowledge, it's
22	should has to include a lot of preclinical	22	the best we have.
23	studies in appropriate animal models, in	23	Q. What other polymers are
24	appropriate functional testing, in	24	appropriate for use in a mesh for
	Page 531		Page 533
1	appropriate textile characteristic and then	1	implantation in the treatment of stress
2	you may get a good impression which design of	2	urinary incontinence?
3	this of your device you want to have is	3	A. I cannot answer. This is a
4	has the lowest risk.	4	very general question. There are a lot of
5	Q. So first thing you mentioned	5	polymers, experimental. We're working on
6	preclinical studies.	6	polymers and other polymers so there are a
7	Is that animal testing?	7	lot of other maybe a lot of other
8	A. It can be in vitro testing. It	8	alternatives. There are some literature
9	can be animal testing.	9	providing new materials but in the moment
10	Q. Do you need both?	10	from my to my knowledge, PVDF has the best
11	A. Yes.	11	results.
12	Q. And the in vitro testing is	12	Q. Okay.
13	what?	13	A. But I cannot give you a
14	A. In vitro testing is maybe it's	14	complete list of all alternative possible
15	the counting of particle loss after	15	alternatives.
16	manufacturing. It can be the behavior in	16	Q. Can you give me a list of three
17	liquids, the degradation, the combination of	17	possible alternatives?
18	these materials with some cells, what happens	18	A. I cannot give you a list of one
19	there, what is the overgrowth. A lot of	19	alternative that is better than PVDF.
20	questions can be addressed in this field.	20	Q. And I know that.
21	Q. Okay. And do you need to do	21	What I asked you is there
22	the in vitro and animal testing before you do	22	A. There are some polyimides,
23	the function testing?	23	polyulitars. These are classes where you can
24	A. Everything has to be in	24	try to look to see alternatives.

49 (Pages 530 to 533)

	Page 534		Page 536
1	Q. Is it your opinion today that	1	comment on polypropylene in general.
2	polypropylene is not an appropriate mesh for	2	Q. I understand that.
3	implantation for the treatment of stress	3	And, Doctor, you have to start
4	urinary incontinence?	4	somewhere and choosing the textile is a
5	A. I think some minutes ago I	5	pretty fundamental issue for any mesh that
6	already said that the word "appropriate"	6	you might use, you agree with that?
7	is makes it impossible for me to say yes.	7	MR. ANDERSON: You mean the
8	Q. Is it your opinion to a	8	polymer?
9	reasonable degree of scientific and medical	9	MR. THOMAS: Yeah, that's what
10	certainty that the use of polypropylene in	10	I meant.
11	meshes for the treatment of stress urinary	11	QUESTIONS BY MR. THOMAS:
12	incontinence is unreasonably dangerous?	12	Q. Doctor, you have to start
13	A. Unreasonable dangerous? Has to	13	somewhere and choosing the appropriate
14	be seen in regard to the specific situation	14	polymer is an important first step in the
15	of the benefits and risks. If you use this	15	design of any mesh, would you agree with
16	implant of polypropylene in an 80-year-old	16	that?
17	patient, I will not expect that you will	17	A. Yeah. I would agree that this
18	experience any problem just because of	18	is a first step because then it leads you to
19	degradation within the next one year. So	19	further decisions.
20	it	20	Q. And even a PVDF polymer can be
21	Q. Do you have a	21	designed in a way that's unreasonably
22	A. I cannot give a general	22	dangerous, do you agree?
23	statement to this.	23	A. Definitely, yeah.
24	Q. Okay. Do you have an opinion	24	Q. And so as I understand your
	Page 535		Page 537
1	to a reasonable degree of scientific and	1	position for use in medicine today, either
2	medical certainty whether it's appropriate to	2	PVDF or polypropylene are appropriate or
3	use polypropylene mesh in hernia repair?	3	excuse me, are not unreasonably dangerous if
4	A. The same objection as before,	4	designed correctly?
5	the term "appropriate."	5	A. Again, there is this
6	Q. Do you have an opinion	6	inappropriate. It depends on what you're
7	A. Makes it difficult or	7	looking. You can create some acceptable
8	impossible for me.	8	textile structures of both, of polypropylene
9	Q. Do you have an opinion to a	9	and PVDF. You will find some different risks
10	reasonable degree of scientific and medical	10	if you compare these two.
11	certainty as to whether the use of	11	Q. Doctor, what is Exhibit A to
12	polypropylene in hernia repair is	12	your report? That's it right there. Those
13	unreasonably dangerous?	13	images.
14	A. The my present opinion is	14	A. These images?
15	that it is not so dangerous that it should be	15	MR. ANDERSON: That's
16	forbidden in today to have to use it and,	16	Exhibit A?
17	therefore, I'm convinced that it is tolerable	17	MR. THOMAS: I think.
18	or acceptable to use polypropylene in	18	MR. ANDERSON: A was his CV.
19	medicine.	19	MR. THOMAS: I am sorry, then
20	Q. Okay.	20	Exhibit C. I apologize.
21	A. But if I may, it depends on the	21	QUESTIONS BY MR. THOMAS:
22	structure.	22	Q. What is Exhibit C to your
23	Q. Right.	23	let me start over again so I get a good
24	A. So it's not a general free	24	question and you give me a good answer.

50 (Pages 534 to 537)

	Page 538		Page 540
1	Doctor, what is Exhibit C to	1	132 slides?
2	Exhibit 11?	2	A. You're right. I'm not a
3	A. Exhibit C is a collection of	3	mathematical expert. It's a big number.
4	images I made from histological sections I	4	Q. Do you know who prepared the
5	received, and I received HE stainings and	5	slides?
6	stainings with S100.	6	A. Professor Kreutzer. I received
7	Q. Okay. Now, did you create the	7	a note that he prepared this with some
8	images that are in Exhibit C?	8	numbers so that I can check whether the
9	A. Yes, myself.	9	number of this data sheet was the same as on
10	Q. And what did you receive	10	the slide, on the
11	strike that.	11	Q. Did you have any interaction
12	I take it you received certain	12	with Dr. Kreutzer about how to prepare these
13	materials from Mr. Anderson that allowed you	13	slides?
14	to make these images, correct?	14	A. Not directly.
15	A. I received complete stainings	15	Q. Did you provide information to
16	in a box, each explant were prepared with the	16	anybody to give to Dr. Kreutzer about how to
17	three stainings, three sections.	17	prepare these slides?
18	Q. So by the time you received	18	MR. ANDERSON: Other than
19	them, the slides had already been stained?	19	conversations with me?
20	A. Yes.	20	QUESTIONS BY MR. THOMAS:
21	Q. And what stainings were done?	21	Q. Let me ask it this way.
22	A. HE, this is this one with the	22	Doctor, do you know how
23	red color, and there is an additional	23	Dr. Kreutzer prepared these slides?
24	staining with a specific antibody S100 that	24	MR. ANDERSON: Objection to
	Page 539		Page 541
1	marks nerves or nerval structures. This is a	1	form.
2	link to a brown color so in these you have	2	Go ahead.
3	this brown color where the S100 is positive.	3	THE WITNESS: I don't know in
4	Q. Okay. Is the HE two different	4	detail, but this staining HE is a
5	stains or just one?	5	normal procedure for every
6	A. No, it's two.	6	pathological department and the doing
7	Q. Okay.	7	of S100 staining is a it's a
8	A. Two.	8	standard procedure. Maybe I can use
9	Q. So you have one two	9	the word "standard" in this context.
10	A. No, it is two colors that are	10	It is published in all of the reports
11	brought to one section. So it's a counter	11	where we presented these data. It is
12	staining.	12	no specific knowledge to do these two.
13	Q. You told me, I thought, that	13	QUESTIONS BY MR. THOMAS:
14	you had three slides?	14	Q. What's Dr. Kreutzer's training,
15	MR. ANDERSON: Three of each.	15	if you know? I've forgotten.
16	THE WITNESS: Three of each.	16	A. He's pathologist.
17	Three HE from patient or from case	17	Q. That's what I thought.
18	one, and three S100 from case one.	18	And he's in Connecticut.
19	QUESTIONS BY MR. THOMAS:	19	Have you ever met him?
20	Q. I see.	20	A. No.
21	So you have six slides for each	21	Q. Spoken to him?
22	patient?	22	A. No.
	A. Yes.	23	Q. Did you have any communication
23 24	Q. So you have 66 no, you have	24	with Dr. Kreutzer at all about the slides

51 (Pages 538 to 541)

	Page 542		Page 544
1	that he presented to you?	1	In the middle of the first image on
2	A. No.	2	Exhibit C, there's a measurement of
3	Q. Have you ever seen any written	3	168.53 microns.
4	analysis by Dr. Kreutzer of the images that	4	Can you tell from looking at
5	are attached as Exhibit C to your report?	5	this image what the magnification is?
6	A. No.	6	A. The magnification would be 40
7	Q. Tell me again what an HE slide	7	or 100.
8	is.	8	Q. Okay. Now
9	A. HE slide is a staining of cells	9	A. When I saved the images, I name
10	and of extra cellular matrix, mainly of	10	it so usually I get it from the name.
11	collagen. So you have a blue color for the	11	Q. I believe that one doesn't have
12	nucleus of the cells to identify the cells	12	any scale on it at all.
13	and you have a red staining mainly for the	13	A. Yeah, sometimes I forgot it.
14	collagen and, yeah.	14	Sorry. So 200 no, 500, 50, this is the
15	Q. Let's go to the very first	15	highest magnification. This is 400, then
16	slide that you have, very first image that	16	this is 40. 40. 40 fold magnification.
17	you have on Exhibit C.	17	Q. And how did you conclude that?
18	And down in the lower right	18	A. Because I've seen there one
19	there is a scale of 500 microns, correct?	19	with the highest magnification and this was
20	A. Yes.	20	400. And so in this the scale was only 50
21	Q. And what's the magnification of	21	and here we have 500 so it is one-tenth.
22	this, do you know?	22	Q. Now, you made these images
23	A. I don't know in this, but when	23	yourself from a scanning electron microscope?
24	I made the image there, I was asked I	24	A. No, from a conventional light
	Page 543		Page 545
1	usually took the 40 magnification, 100, 200,	1	microscope.
1 2	usually took the 40 magnification, 100, 200, 400. These are the options at the	1 2	microscope. Q. And where did you have that
	400. These are the options at the		Q. And where did you have that
2		2	•
2 3	400. These are the options at the microscope. And then the analyzing system	2 3	Q. And where did you have that light microscope?
2 3 4	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there	2 3 4	Q. And where did you have that light microscope? A. In our lab on the third level
2 3 4 5	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there,	2 3 4 5	Q. And where did you have that light microscope? A. In our lab on the third level in room 45 at no, ward 45, room 1. On a
2 3 4 5 6 7 8	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification.	2 3 4 5 6	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.
2 3 4 5 6 7 8 9	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a	2 3 4 5 6 7 8 9	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I
2 3 4 5 6 7 8 9	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of	2 3 4 5 6 7 8 9	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts
2 3 4 5 6 7 8 9 10	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or	2 3 4 5 6 7 8 9 10	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.
2 3 4 5 6 7 8 9 10 11	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.	2 3 4 5 6 7 8 9 10 11	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.  A. It's mainly collagen, yeah.
2 3 4 5 6 7 8 9 10 11 12 13	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.  Q. Well, there are different I	2 3 4 5 6 7 8 9 10 11 12	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.  A. It's mainly collagen, yeah.  Q. And what does the tan area
2 3 4 5 6 7 8 9 10 11 12 13 14	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.  Q. Well, there are different I see different scales throughout these	2 3 4 5 6 7 8 9 10 11 12 13	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.  A. It's mainly collagen, yeah.  Q. And what does the tan area represent?
2 3 4 5 6 7 8 9 10 11 12 13 14 15	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.  Q. Well, there are different I see different scales throughout these photographs.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.  A. It's mainly collagen, yeah.  Q. And what does the tan area represent?  A. The tan?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.  Q. Well, there are different I see different scales throughout these photographs.  A. It's 40, 100, 200, 400	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.  A. It's mainly collagen, yeah.  Q. And what does the tan area represent?  A. The tan?  Q. This area over here, I call
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.  Q. Well, there are different I see different scales throughout these photographs.  A. It's 40, 100, 200, 400 magnification.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.  A. It's mainly collagen, yeah.  Q. And what does the tan area represent?  A. The tan?  Q. This area over here, I call tan.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.  Q. Well, there are different I see different scales throughout these photographs.  A. It's 40, 100, 200, 400 magnification.  So as I recall, these are the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.  A. It's mainly collagen, yeah.  Q. And what does the tan area represent?  A. The tan?  Q. This area over here, I call tan.  A. Here?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.  Q. Well, there are different I see different scales throughout these photographs.  A. It's 40, 100, 200, 400 magnification.  So as I recall, these are the four different magnifications and there will	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.  A. It's mainly collagen, yeah.  Q. And what does the tan area represent?  A. The tan?  Q. This area over here, I call tan.  A. Here?  Q. Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.  Q. Well, there are different I see different scales throughout these photographs.  A. It's 40, 100, 200, 400 magnification.  So as I recall, these are the four different magnifications and there will be correspondingly four different scales	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.  A. It's mainly collagen, yeah.  Q. And what does the tan area represent?  A. The tan?  Q. This area over here, I call tan.  A. Here?  Q. Yes.  What is that?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.  Q. Well, there are different I see different scales throughout these photographs.  A. It's 40, 100, 200, 400 magnification.  So as I recall, these are the four different magnifications and there will be correspondingly four different scales here.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.  A. It's mainly collagen, yeah.  Q. And what does the tan area represent?  A. The tan?  Q. This area over here, I call tan.  A. Here?  Q. Yes.  What is that?  A. There is nothing. No cells
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.  Q. Well, there are different I see different scales throughout these photographs.  A. It's 40, 100, 200, 400 magnification.  So as I recall, these are the four different magnifications and there will be correspondingly four different scales here.  Q. Okay. What does this tell you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.  A. It's mainly collagen, yeah.  Q. And what does the tan area represent?  A. The tan?  Q. This area over here, I call tan.  A. Here?  Q. Yes.  What is that?  A. There is nothing. No cells there.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.  So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.  Q. Well, there are different I see different scales throughout these photographs.  A. It's 40, 100, 200, 400 magnification.  So as I recall, these are the four different magnifications and there will be correspondingly four different scales here.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And where did you have that light microscope?  A. In our lab on the third level in room 45 at no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.  Q. Thank you, Doctor.  The first image to Exhibit C, I believe you said the red area depicts collagen.  A. It's mainly collagen, yeah.  Q. And what does the tan area represent?  A. The tan?  Q. This area over here, I call tan.  A. Here?  Q. Yes.  What is that?  A. There is nothing. No cells

52 (Pages 542 to 545)

	Page 546		Page 548
1	A. No tissue on this.	1	A. I have the information of this
2	Q. Does that mean the slide does	2	table, yeah, but usually I look to the images
3	not contain any tissue as you're looking at	3	and without any knowledge so in a blind
4	it?	4	fashion.
5	A. Yes.	5	Q. I understand.
6	Q. Okay. Does that mean that the	6	Did you prepare the table which
7	area marked as 168.53 is at the right extreme	7	is prepared as the last page of your report?
8	of the sample you're analyzing?	8	MR. ANDERSON: I prepared it in
9	A. In this picture, yes.	9	accordance with the chain of custody
10	Q. And what is the area marked as	10	forms.
11	168.53?	11	MR. THOMAS: Did you prepare
12	A. This is a fragment of the	12	all of it?
13	polymer fibers. When looking to the slides,	13	MR. ANDERSON: Well, I had to
14	the first thing I try to do is to measure the	14	get his ID number and the Jordi ID
15	diameter of these fragments so I know that	15	number and the Steelgate specimen
16	there is a the cutting of these fragments	16	number and all of the information that
17	is not directly horizontal to the course of	17	Steelgate had in conjunction with the
18	the fibers.	18	various other information so that I
19	But to have a rough impression	19	could assimilate his the
20	what is a diameter of the fiber that it is in	20	information that he provided on his ID
21	the area that I expect to be there.	21	number, and then everything from N to
22	Q. Doctor	22	R he prepared or gave the information.
23	A. So that is around 150 microns.	23	So the reason for doing this
24	Q. Okay. Now, do you believe that	24	was to make it A, easier to keep up
	Page 547		Page 549
1	this is this a mesh fiber, is that what	1	with the chain of custody so that you
2	you're saying?	2	could see where it went from explant
3	A. It is consistent with the	3	to his hands. It would also be
4	with the fact that the that this fiber has	4	consistent with the chain of custody
5	the diameter of 160. If I would have seen a	5	forms that Mr. Snell and I agreed to
6	polymer with only 4 microns from this, then I	6	and so it would make it easier at this
7	would have some doubts that it's the right	7	deposition for you if you wanted to
8	material.	8	look at a particular device or
9	But this finding is consistent	9	whatever and be able to compare them.
10	with a polypropylene fiber of a TVT®-O or	10	So that was the effort that I
11	TVT®.	11	put forth in order to try to put the
12	Q. So what does this mean to you?	12	information of all of the slides in
13	What's the significance of this	13	one spot for both you and I.
14	finding on this slide which is the first	14	QUESTIONS BY MR. THOMAS:
15 16	slide of Exhibit 3 to your report?	15	Q. And the identifier for these
17	A. It's consistent with the	16  17	slides is in the lower left-hand corner; is that correct?
18	assumption that it's a TVT®-O or a TVT®. If it would have been 250 or 300 microns, then I	18	A. That is the number or the
19	should to rethink about it. It's just a	19	coating that I found on the slide, on the
20	confirmation that I really just got what was	20	stainings, yeah.
21	written in the table.	21	Q. Was this number already on the
22	Q. And so you're consulting a	22	staining or did you have to add it to this
23	table as you review these images; is that	23	document?
24	correct?	24	A. No. I used I used I used
	COLLECT.		11. 110. 1 ubcu

53 (Pages 546 to 549)

	Page 550		Page 552
1	the number from the stainings from Professor	1	cell wall around, and in these cells, the
2	Kreutzer and then I placed them or I named	2	nucleus is at the bottom and you have an area
3	the images according to this number and added	3	in the middle where the fatty acids have been
4	the sort of staining and added the	4	and, therefore, it is bright. You don't see
5	magnification in the name of the slides.	5	significant structures in the fat tissue.
6	Q. Did you receive all did you	6	Q. Okay. So you showed me the fat
7	see is 22 slides all you received or did	7	tissue and the collagen and you've also shown
8	you receive any more than that? Excuse me,	8	me the polymer fiber.
9	strike that.	9	What else is of significance in
10	Did you receive slides from 22	10	the first slide of Exhibit C?
11	separate patients, or did you receive more	11	MR. ANDERSON: Objection to the
12	than that?	12	form of the question.
13	A. No, 21, 22 cases, different	13	THE WITNESS: I wouldn't point
14	cases.	14	out any others.
15	MR. THOMAS: Can we take a	15	QUESTIONS BY MR. THOMAS:
16	break a second, please?	16	Q. Okay. When you looked at the
17	MR. ANDERSON: Sure.	17	22 different patients you said that you
18	(Off the record at 2:42 p.m.)	18	developed some parameters.
19	QUESTIONS BY MR. THOMAS:	19	What does that mean?
20	Q. Doctor, looking again at the	20	A. The parameters I want in
21	first image of Exhibit C to your report, what	21	general, this looking at these samples I
22	of significance do you find in this image	22	want to get a confirmation that what we have
23	related to adverse reaction to mesh?	23	seen in all these animal slides, what we have
24	A. Just to explain I looked	24	seen in the human explants from the abdominal
	Page 551		Page 553
1	through all of these stainings there and I	1	wall that this is confirmed by explants
2	define some parameters which I've been	2	provided by Professor Kreutzer, as well and,
3	looking at and these I put in this table and	3	therefore, the first is that I look to the
4	then I made some exemplary images of every	4	fiber size, I try to measure it, that I
5	case. It's even at this low magnification,	5	really am sure that it's a monofilament a
6	it is just one small part of the section.	6	monofilament in a size that has to be
7	The section is much bigger, and, therefore, I	7	expected there, that was the first.
8	just want to cover the general impression of	8	The second is the bridging,
9	any of these findings that are on the table	9	whether I see pores, the room between two
10	by these images.	10	filaments that are filled with fat and I made
11	So what you see here is	11	a coating to get or to differentiate whether
12	appearance of a polymer fiber in a size that	12	these pores are frequently seen, rarely seen,
13	we expected. You see some fat tissue there	13	always seen or never seen.
14	at the lower part and you see extensive	14	The next was whether there was
15	tissue here very close to this fiber. And	15	some sign of folding on shrinkage. The main
16	this is indicated by the red color. This is	16	structure should be if there is no folding
17	the content of this image.	17	and shrinkage, should be in a plain way
18	Q. Is fat tissue and collagen the	18	detectable in these stainings or shouldn't be
19 20	same thing?	19 20	in a folded or in a wave-like position.
21	A. No. The fat tissue is this	20	If I saw somewhere at the mesh
22	lower part by the fixation, by the staining.	22	that there is a doubling of the structures or
23	Essentially the fatty liquids are removed so	23	there is a configuration that cannot be
24	you have almost empty spaces there and you can identify fat cells that you only have the	24	explained by a plain positioning, then I marked it with a yes.
4	can ruching far cens mar you only have me	4	marked it with a yes.

54 (Pages 550 to 553)

	Page 554		Page 556
1	And then finally I looked at	1	Slides.
2	the S100 stainings, whether there are some	2	THE WITNESS: Slides.
3	nerves in the within the scar area of	3	The data explants from
4	surrounding the mesh because in former times,	4	Professor Klosterhalfen.
5	there has been the discussion the big nerves	5	QUESTIONS BY MR. THOMAS:
6	are not in this area, therefore, it is	6	Q. That's better. I thought he
7	impossible that the mesh interacts with some	7	said explants. That's so the only thing
8	nerves and for this purpose, I just mentioned	8	you received from Dr. Kreutzer were the
9	whether there are some nerves, yes or not,	9	slides?
10	and in fact, you see nerves in this small	10	A. Yes.
11	nerves that cannot be visualized by the	11	Q. Now, the information that you
12	surgeon during the operation, but you have	12	received from Dr. Klosterhalfen was the data
13	there some nerve structures very close to	13	that he generated from his analysis of his
14	this wound.	14	explant collection, correct?
15	These are the four points and	15	A. No, I got his data and I had
16	every slide I analyzed to get an opinion on	16	the opportunity to have a look at some
17	these four things, for every case.	17	stainings in Düren as well.
18	Q. The parameters that you've just	18	Q. Okay.
19	described, are those parameters unique to	19	A. So I've seen it.
20	this case?	20	Q. But just so I understand, the
21	A. Yes, unique.	21	stainings that you looked at in Düren were
22	Q. Okay. And why did you pick	22	stainings that Dr. Klosterhalfen had already
23	those parameters?	23	prepared and analyzed; is that true?
24	A. Because the value of this of	24	A. Yes.
	Page 555		Page 557
1	these explants is that they allow me to	1	Q. And reported on his findings
2	confirm that or to test whether what we	2	for those stainings?
3	have seen in the animal tissues, in the human	3	A. Yes, but in the moment, I
4	tissues of the abdominal wall, whether this	4	didn't know it. He just placed these tissues
5	is true for these. I had the data from	5	to me and so, yeah.
6	Professor Klosterhalfen from his explants and	6	Q. Okay.
7	it already indicated that it is similar or	7	A. I could not relate it to the
8	comparable and now I personally have the	8	databases. It was again, it was one way
9	option to test to have it tested at these	9	to test whether this was confirmed in these
10	22 sections.	10	tissues with these explants what we what
11	Yeah, overall, in fact, you see	11	our points of concern are.
12	this extended bridging there, you see that	12	Q. What form did the information
13	the distance between the fibers is less than	13	take that Professor Klosterhalfen gave to
14	these 1,400 microns. So it is it	14	you, the data that you talked about?
15	underlines, again, that it is irrelevant to	15	Is it a chart or is it
16	discuss these 1,400 because if you look to	16	information on the that contains his
17	the tissues, you see this bridging with these	17	information strike that.
18	devices.	18	Did Professor Klosterhalfen
19	Q. Okay. You said a number of	19	give to you a document that detailed his
20	things in your answer I want to talk about.	20	analytical findings from his explant
21	You mentioned you received some	21	collection?
22	explants from Professor Kreutzer; is that	22	A. I had an Excel sheet where he
23	right?	23	had some of his findings.
24	MR. ANDERSON: Objection.	24	Q. Is this the Excel sheet we

55 (Pages 554 to 557)

	Page 558		Page 560
1	talked about last year, the same sort of	1	correlates to the 473, I forget the
2	thing that you have on your computer?	2	number, pelvic floor explants in Düren
3	A. Similar. Similar.	3	that he's referencing now.
4	Q. Is it the same document, just	4	QUESTIONS BY MR. THOMAS:
5	more explants?	5	Q. Okay. And you were relying on
6	A. No. No. We talked last year	6	the data generated by Professor Klosterhalfen
7	about only explants, full explants, of the	7	in part for your opinions that you're giving
8	abdominal wall.	8	from your review of these slides; is that
9	Q. Okay.	9	fair?
10	A. Now it is in other Excel sheet	10	A. There is no I don't
11	for the explants from the pelvic floor.	11	understand whether you see a relation to
12	Q. Okay. And did you analyze the	12	this. We have our experience that bridging
13	data provided to you by Professor	13	is important and so on, and we have tested by
14	Klosterhalfen to understand the complications	14	our own explants. I took the opportunity to
15	which occur from mesh implants in a pelvic	15	have it controlled in Düren. I took the
16	floor?	16	opportunity to have it tested by the data
17	A. I made an analysis of this data	17	sheet of his and then I took the opportunity
18	in regard or to see whether these data	18	to have it tested test our opinions, our
19	confirm our opinions and our experience from	19	experience at the 21 cases that I got from
20	the abdominal call.	20	Professor Kreutzer and finally eventually I
21	Q. In addition to the Excel	21	took the opportunity to check this at the
22	spreadsheet that you have of Professor	22	last 22nd of this case.
23	Klosterhalfen's findings, you also went over	23	So it is subsequently permanent
24	to Düren and looked at some slides, correct?	24	confirm or looking for a confirmation or a
	Page 559		Page 561
1	A. Yes.	1	rejection of what we know.
2	Q. Did you look at all of the	2	Q. And just so I understand, this
3	slides that he had?	3	is the collection of explants maintained by
4	A. No.	4	Professor Klosterhalfen in Düren that I'm not
5	Q. How many did you look at?	5	allowed to see; is that true?
6	A. About 20 to 30.	6	MR. ANDERSON: Objection to
7	Q. Why did you look at 20 to 30	7	form.
8	slides?	8	MR. THOMAS: It's true, isn't
9	A. To have it seen by my personal	9	it?
10	eyes.	10	QUESTIONS BY MR. THOMAS:
11	Q. Okay. Have you produced to us	11	Q. This is the collection
12	the Excel spreadsheet with the data that you	12	protected by German privacy laws that limits
13	received from Professor Klosterhalfen?	13	and prohibits me from looking at it without
14	A. Not that I recall.	14	permission from the patient.
15	MR. ANDERSON: You have it.	15	Do you know the answer to that?
16	It was the one that we produced	16	A. I have read it, but I'm not
17	to you right before Klosterhalfen's	17	familiar
18	depo and that was the one that Henry	18	Q. I'm talking about whether I can
19	also gave to you at the depo or showed	19 20	see it.
20 21	you at the depo.	20	A. What?
22	MR. THOMAS: That's the	21	I'm not an expert what are the
23	Klosterhalfen exhibit from the BARD	23	legal steps to go over there and to do so. I
	litigation.  MR. ANDERSON: Correct. That	24	read it in the depo form.  Q. Now, when you were at the
24			

56 (Pages 558 to 561)

	Page 562		Page 564
1	university, you were a surgeon and you	1	to get an impression whether there are some
2	practiced as a surgeon until 2006, correct?	2	nerves or not. And we're not or the main
3	A. I am a surgeon and practiced	3	focus of our research was not to specify
4	until 2006.	4	there whether it's neurofilaments or there
5	Q. You did not work for the	5	are so many different options to use
6	Institute of Pathology?	6	antibodies against nerves so we selected
7	A. No.	7	S100.
8	Q. And that was Dr. Klosterhalfen	8	Q. Okay. You and
9	who worked in the Institute of Pathology and	9	Dr. Klosterhalfen decided which staining
10	collaborated with you on your work?	10	method to use?
11	A. Yes.	11	A. Mainly he decided. I think we
12	Q. Are you permitted at the	12	started at the in the '90s and he proposed
13	hospital where you work to sign pathology	13	to use \$100 because this was established in
14	reports?	14	the Institute for Pathology and we got good
15	A. No, I'm not permitted to do.	15	images and good information from this and,
16	Q. Did you have a residency in	16	therefore, it is still widely used and we are
17	pathology?	17	satisfied with it.
18	A. No.	18	Q. Doctor, isn't it true that
19	Q. Did you have a fellowship in	19	normal vaginal tissue contains nerve fibers?
20	pathology?	20	A. Yes.
21	A. No.	21	Q. And so the fact that your
22	Q. Have you ever been an editor or	22	staining picks up nerve fibers is not
23	reviewer of a pathology journal?	23	remarkable by itself?
24	A. No.	24	A. As I told you, the intention to
	Page 563		Page 565
1	Q. Are you familiar with the	1	look for these fibers has been discussions we
2	staining technique known as neurofilament	2	had that someone is standing up and said,
3	staining?	3	okay, it cannot be that someone some
4	A. I've read it and I know that it	4	patient has some pain because the big nerves
5	exists.	5	we took care during the operation and the big
6	Q. Have you ever used	6	nerves are far away and that just to
7	neurofilament staining?	7	demonstrate to an audience that there are
8	A. Not that I recall in the recent	8	these tiny nerves that cannot be seen by any
9	time.	9	surgeon when he's in this field, we just made
10	Q. What is the purpose of	10	it for this purpose and, therefore, we didn't
11	neurofilament staining?	11	make any further analysis. Just yes, no, and
12	A. It's another option to	12	as you said earlier, everyone knows that
	visualize nerval structures. More specific.	13	these nerves are there, but some of my
13			
14	Q. More specific.	14	colleagues they don't want to know it maybe.
14 15	Q. More specific. It can okay. Did you ask	15	Q. What do you mean, "They don't
14 15 16	Q. More specific. It can okay. Did you ask for neurofilament staining of the samples	15 16	Q. What do you mean, "They don't want to know it"? I don't understand.
14 15 16 17	Q. More specific. It can okay. Did you ask for neurofilament staining of the samples that you looked at?	15 16 17	Q. What do you mean, "They don't want to know it"? I don't understand.  A. They ignore this fact sometimes
14 15 16 17 18	Q. More specific. It can okay. Did you ask for neurofilament staining of the samples that you looked at? A. No.	15 16 17 18	Q. What do you mean, "They don't want to know it"? I don't understand. A. They ignore this fact sometimes in discussions.
14 15 16 17 18 19	Q. More specific. It can okay. Did you ask for neurofilament staining of the samples that you looked at? A. No. Q. Why not?	15 16 17 18 19	Q. What do you mean, "They don't want to know it"? I don't understand.  A. They ignore this fact sometimes in discussions.  Q. They ignore the presence of
14 15 16 17 18 19 20	Q. More specific. It can okay. Did you ask for neurofilament staining of the samples that you looked at? A. No. Q. Why not? A. I didn't ask.	15 16 17 18 19 20	Q. What do you mean, "They don't want to know it"? I don't understand. A. They ignore this fact sometimes in discussions. Q. They ignore the presence of nerves?
14 15 16 17 18 19 20 21	Q. More specific. It can okay. Did you ask for neurofilament staining of the samples that you looked at? A. No. Q. Why not? A. I didn't ask. Q. Why not?	15 16 17 18 19 20 21	Q. What do you mean, "They don't want to know it"? I don't understand. A. They ignore this fact sometimes in discussions. Q. They ignore the presence of nerves? A. Of these small, tiny nerves
14 15 16 17 18 19 20 21 22	Q. More specific. It can okay. Did you ask for neurofilament staining of the samples that you looked at? A. No. Q. Why not? A. I didn't ask. Q. Why not? A. Because in our experience, we	15 16 17 18 19 20 21 22	Q. What do you mean, "They don't want to know it"? I don't understand.  A. They ignore this fact sometimes in discussions.  Q. They ignore the presence of nerves?  A. Of these small, tiny nerves there, yeah.
14 15 16 17 18 19 20 21	Q. More specific. It can okay. Did you ask for neurofilament staining of the samples that you looked at? A. No. Q. Why not? A. I didn't ask. Q. Why not?	15 16 17 18 19 20 21	Q. What do you mean, "They don't want to know it"? I don't understand. A. They ignore this fact sometimes in discussions. Q. They ignore the presence of nerves? A. Of these small, tiny nerves

57 (Pages 562 to 565)

	Page 566		Page 568
1	identification.)	1	of some endothelial cells forming vessels.
2	QUESTIONS BY MR. THOMAS:	2	Q. And what are fibroblasts?
3	Q. Doctor, I've handed you what's	3	A. Fibroblasts are cells that are
4	been marked as Deposition Exhibit Number 24	4	used to mainly their task is make a
5	and ask you if that's the pathology report	5	deposition of collagen there. They are
6	for Carolyn Lewis?	6	very or if you have an injury or a damage
7	A. Yes.	7	in the tissue, usually the fibroblasts are
8	Q. Thank you. I'm sorry, I didn't	8	called to make an unspecific repair by
9	hear your answer, I apologize.	9	forming scar tissue in this field of damage
10	A. I didn't get the question.	10	and defect. It's they are the cells
11	MR. ANDERSON: He didn't	11	mainly responsible for the scar tissue and
12		12	has to be differentiated from more
13	answer. He was still looking. QUESTIONS BY MR. THOMAS:	13	
14		14	specialized cells as fat tissue, for example.
	Q. Oh, okay.		Q. And what is what are
15	Did the pathology report inform	15	what's collagen?
16 17	your opinions at all about the tissue	16	A. Collagen is a protein. There
	reaction Ms. Lewis had to the mesh implant?	17	are 13, 16 different collagens. Mainly we
18	A. I didn't get the did the	18	have to deal with collagen 1. That is a
19	pathology no, first of all, I looked	19	protein of several helixes and this is
20	afterwards to this pathology report, and as I	20	responsible for the stability of fascia and
21	tried to explain, I'm looking to bridging,	21	of skin. It has to be separated from
22	folding, nerve contact and this is not	22	collagen type 3. That is a collagen that
23	included here. But what they describe is the	23	appears usually at the early days of wound
24	usual appearance and, unfortunately, it's a	24	healing and later on is replaced by this
	Page 567		Page 569
1	usual report given by pathology when they get	1	stable collagen 1. An increased amount of
2	an implant, but they never looked to the	2	collagen 3 is an indicator of an impaired
3	pores or the extent of the scar tissue.	3	wound healing and indicator for high risk for
4	So I would expect a similar	4	recurrent hernia.
5	report in Germany.	5	Q. Is the presence of fibroblasts,
6	Q. And just to be clear, there's	6	microcapillary cells and collagen bundles
7	nothing remarkable in Exhibit 4 which is the	7	inconsistent with the formation of scar
8	pathology report to Ms. Lewis that the	8	plate?
9	pathologist found after the explantation to	9	A. Complete different things.
10	suggest any remarkable tissue reaction with	10	They are they contribute to the extent of
11	the mesh; is that true?	11	a scar.
12	A. It is too unspecific. It just	12	Q. But the presence of
13	confirms that the routine pathology is not	13	MR. ANDERSON: Were you through
14	able to give a detailed description of the	14	with your answer?
15	tissue reaction to a device.	15	THE WITNESS: What?
16	Q. Now, are you able to detect	16	MR. ANDERSON: Were you through
17	fibroblasts as you look at these images?	17	with your answer?
18	A. Yes, yes, you can see them.	18	THE WITNESS: Yes.
19	Q. Are you able to detect	19	QUESTIONS BY MR. THOMAS:
20	microcapillary cells?	20	Q. But the presence of
21	A. Microcapillary, endothelial,	21	fibroblasts, microcapillary vessels and
22	yes, you can see it.	22	collagen bundles are an indication of proper
23 24	Q. What is a microcapillary cell?	23 24	tissue integration, correct?  A. You can't decide from the

58 (Pages 566 to 569)

	Page 570		Page 572
1	presence of these cells either whether it's a	1	images, but I have to look whether all of
2	scar plate or a scar net. If you stick to	2	these are here or
3	these words or whether it's proper or whether	3	MR. THOMAS: Do you know, Ben?
4	it's inadequate, it's just described that	4	I don't want to spend my time looking
5	there is some scar reaction there, but it	5	through the report and I'm just
6	gives it doesn't give you any hint whether	6	curious. I'll want copies of the I
7	it's sufficient, necessary or too much scar.	7	will want copies of these if they're
8	Q. Have you read the expert report	8	not the same.
9	of Dr. Zing?	9	MR. ANDERSON: I don't know if
10	A. Yes.	10	all of them are the same, but
11	Q. Okay. And do you agree with	11	certainly have an agreement with Burt
12	the findings of Dr. Zing?	12	that we can that we need to swap
13	MR. ANDERSON: Well, objection.	13	slides. Zing's come to me, mine go to
14	Which ones? It's a long report.	14	you.
15	Which ones?	15	MR. THOMAS: Okay. I didn't
16	QUESTIONS BY MR. THOMAS:	16	know that.
17		17	MR. ANDERSON: Yeah, you-all
18	Q. Just generally, do you agree with the findings of Dr. Zing?	18	need to talk more.
19	č č	19	Yeah, so you'll have the
20	A. I need to go to the paper otherwise.	20	
21		21	opportunity to or have your guy look at ours and I need your guy I
	Q. Do you have a recollection of	22	, , ,
22 23	anything in the report that you disagreed	23	need yours, too. We just need to get
24	with?	24	that worked out.
24	MR. ANDERSON: Again,	24	MR. THOMAS: You need the
	Page 571	_	Page 573
1	objection.	1	slides
2	MR. THOMAS: I understand.	2	MR. ANDERSON: The slides.
3	MR. ANDERSON: Without letting	3	MR. THOMAS: somebody else
4	him see the report.	4	has. They're not mine.
5	THE WITNESS: My rough	5	MR. ANDERSON: So they can be
6	recollection was that he described a	6	observed by someone else that are not
7	lot of things that I can agree to, but	7	yours.
8	my impression was that he didn't have	8	So I can't really answer this
9	a or that his experience in	9	question.
10	comparing tissue reaction to different	10	MR. THOMAS: Okay. We'll just
11	textile structures, that this his	11	make a record of that fact. We're not
12	experience is limited.	12	sure that the images that appear on
13	QUESTIONS BY MR. THOMAS:	13	pages 70, 71, 72 and 73 and 74 also
14	Q. Okay.	14	appear in the appendix C.
15	A. And that his statements whether	15	Mr. Anderson advises that there's an
16	it is a about the quantity in comparison	16	arrangement whereby we will exchange
17	to others, that there are only very few	17	slides so that Dr. Zing will have an
18	remarks on it. But otherwise we have to go	18	opportunity to review what
19	to	19	Dr. Klinge's reviewed, and Dr. Klinge
20	Q. Okay. Let's go to page 70 of	20	will have an opportunity to review
21	your report.	21	what Dr. Zing reviewed; is that
22	Now, are the images of page 70	22	correct?
		22 23 24	

59 (Pages 570 to 573)

	Page 574		Page 576
1	photos and taking up your time,	1	It has been possible to detect polymer
2	without comparing all of these, I know	2	particles better because they start to get
3	that some of them are certainly in the	3	bright there in this.
4	back.	4	Q. Let's stay with the three
5	MR. THOMAS: And probably by	5	images on page 71 for right now.
6	definition since there are so many of	6	As you look at the three images
7	them, some of them aren't.	7	on page 71
8	MR. ANDERSON: I don't know if	8	A. Yeah.
9	that's true.	9	Q is there anything about
10	QUESTIONS BY MR. THOMAS:	10	those images that suggests to you that there
11		11	
12	Q. So going to page 70, do you	12	is inadequate tissue integration strike
	know if the images from page 70 are from		that.
13	Carolyn Lewis? And the reason why I ask is	13	Looking at the images on
14	on the next page, you refer to her by code	14	page 71, the three right there in a row, is
15	name on page 71 for the first time.	15	there anything about those three images that
16	A. Yes. And, therefore, the first	16	suggests to you that there's an inappropriate
17	images are not from this case. These are	17	inflammatory response to the mesh?
18	from the first 21 cases. And then later on,	18	MR. ANDERSON: Objection to the
19	one week later, I got the case BAL 13-23 and,	19	form.
20	therefore, the first images are not from her.	20	Go ahead.
21	MR. ANDERSON: It's BAL 13-23.	21	THE WITNESS: What you see in
22	QUESTIONS BY MR. THOMAS:	22	this is in the middle part, it's a
23	Q. Why didn't you say Carolyn	23	higher magnification than you see some
24	Lewis in your report?	24	inflammatory infiltrate close to the
	Page 575		Page 577
1	MR. ANDERSON: Objection.	1	polymer that is the typical foreign
2	THE WITNESS: No specific	2	body reaction.
3	reason for it.	3	QUESTIONS BY MR. THOMAS:
4	QUESTIONS BY MR. THOMAS:	4	Q. I am sorry, that's a typical
5	Q. Okay.	5	foreign body reaction?
6	A. When I got all this all	6	A. Yeah.
7	these numbers, I have no problems to use	7	Q. Okay. Thank you.
8			
	these numbers. If I take numbers of names	8	- · · · · · · · · · · · · · · · · · · ·
9	these numbers. If I take numbers of names here. I'm not allowed I'm not	8	A. Foreign body reaction.
9 10	here, I'm not allowed I'm not	9	A. Foreign body reaction. On the right side, you see that
10	here, I'm not allowed I'm not well-informed about possible consequences	9 10	A. Foreign body reaction. On the right side, you see that there are some fibers, and in between, the
10 11	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I	9 10 11	A. Foreign body reaction.  On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and
10 11 12	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code.	9 10 11 12	A. Foreign body reaction. On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest
10 11 12 13	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code.  Q. Dr. Klinge, so the first images	9 10 11 12 13	A. Foreign body reaction. On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that
10 11 12 13 14	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code. Q. Dr. Klinge, so the first images that relate to Carolyn Lewis appear on	9 10 11 12 13 14	A. Foreign body reaction. On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that there nowhere is a huge area of fat tissue,
10 11 12 13 14 15	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code.  Q. Dr. Klinge, so the first images that relate to Carolyn Lewis appear on page 71?	9 10 11 12 13 14 15	A. Foreign body reaction.  On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that there nowhere is a huge area of fat tissue, but all is a scar tissue there.
10 11 12 13 14 15	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code.  Q. Dr. Klinge, so the first images that relate to Carolyn Lewis appear on page 71?  A. Yeah.	9 10 11 12 13 14 15	A. Foreign body reaction.  On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that there nowhere is a huge area of fat tissue, but all is a scar tissue there.  So overall, this HE staining
10 11 12 13 14 15 16	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code. Q. Dr. Klinge, so the first images that relate to Carolyn Lewis appear on page 71? A. Yeah. Q. Now, what are the three images	9 10 11 12 13 14 15 16	A. Foreign body reaction.  On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that there nowhere is a huge area of fat tissue, but all is a scar tissue there.  So overall, this HE staining confirms that this mesh material completely
10 11 12 13 14 15 16 17	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code. Q. Dr. Klinge, so the first images that relate to Carolyn Lewis appear on page 71? A. Yeah. Q. Now, what are the three images that appear in the middle of page 71?	9 10 11 12 13 14 15 16 17	A. Foreign body reaction.  On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that there nowhere is a huge area of fat tissue, but all is a scar tissue there.  So overall, this HE staining confirms that this mesh material completely is integrated in a scar field.
10 11 12 13 14 15 16 17 18	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code. Q. Dr. Klinge, so the first images that relate to Carolyn Lewis appear on page 71? A. Yeah. Q. Now, what are the three images that appear in the middle of page 71? A. All these are HE stainings and	9 10 11 12 13 14 15 16 17 18	A. Foreign body reaction.  On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that there nowhere is a huge area of fat tissue, but all is a scar tissue there.  So overall, this HE staining confirms that this mesh material completely is integrated in a scar field.  Q. Okay. We talked earlier about
10 11 12 13 14 15 16 17 18 19 20	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code. Q. Dr. Klinge, so the first images that relate to Carolyn Lewis appear on page 71? A. Yeah. Q. Now, what are the three images that appear in the middle of page 71? A. All these are HE stainings and should give you an impression that it's only	9 10 11 12 13 14 15 16 17 18 19 20	A. Foreign body reaction.  On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that there nowhere is a huge area of fat tissue, but all is a scar tissue there.  So overall, this HE staining confirms that this mesh material completely is integrated in a scar field.  Q. Okay. We talked earlier about a scar net or a scar plate?
10 11 12 13 14 15 16 17 18 19 20 21	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code.  Q. Dr. Klinge, so the first images that relate to Carolyn Lewis appear on page 71?  A. Yeah. Q. Now, what are the three images that appear in the middle of page 71? A. All these are HE stainings and should give you an impression that it's only a small part of the tissue there. It's not a	9 10 11 12 13 14 15 16 17 18 19 20 21	A. Foreign body reaction.  On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that there nowhere is a huge area of fat tissue, but all is a scar tissue there.  So overall, this HE staining confirms that this mesh material completely is integrated in a scar field.  Q. Okay. We talked earlier about a scar net or a scar plate?  A. Yeah.
10 11 12 13 14 15 16 17 18 19 20 21 22	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code.  Q. Dr. Klinge, so the first images that relate to Carolyn Lewis appear on page 71?  A. Yeah. Q. Now, what are the three images that appear in the middle of page 71? A. All these are HE stainings and should give you an impression that it's only a small part of the tissue there. It's not a big section that has been stained there. And	9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Foreign body reaction.  On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that there nowhere is a huge area of fat tissue, but all is a scar tissue there.  So overall, this HE staining confirms that this mesh material completely is integrated in a scar field.  Q. Okay. We talked earlier about a scar net or a scar plate?  A. Yeah.  Q. Is it a scar net or a scar
10 11 12 13 14 15 16 17 18 19 20 21	here, I'm not allowed I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code.  Q. Dr. Klinge, so the first images that relate to Carolyn Lewis appear on page 71?  A. Yeah. Q. Now, what are the three images that appear in the middle of page 71? A. All these are HE stainings and should give you an impression that it's only a small part of the tissue there. It's not a	9 10 11 12 13 14 15 16 17 18 19 20 21	A. Foreign body reaction.  On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that there nowhere is a huge area of fat tissue, but all is a scar tissue there.  So overall, this HE staining confirms that this mesh material completely is integrated in a scar field.  Q. Okay. We talked earlier about a scar net or a scar plate?  A. Yeah.

60 (Pages 574 to 577)

	Page 578		Page 580
1	because a scar net would require some fatty	1	MR. ANDERSON: Objection.
2	tissue in between the filaments. And if	2	THE WITNESS: In sweeties, it's
3	you're measuring or looking at the distances	3	perfect. There's some sweets made of
4	between the filaments, the filament is	4	collagen. There, it's great.
5	150 microns and the distance is very close	5	QUESTIONS BY MR. THOMAS:
6	together. So you can suspect that this is at	6	Q. I thought collagen deposition
7	the linking part and not in the middle of the	7	between pores was a good thing.
8	pores, but if you look through the entire	8	Is that not true?
9	section, you always find images like here,	9	A. It depends if you have a wound
10	not the big distances.	10	from a burn, then you get an extensive scar
11	Q. Okay. And when you get these	11	formation, and I don't know whether you have
12	slides, has the mesh does the mesh	12	seen these images of contractures for these
13	typically fall out of the slides before you	13	patients. It is a catastrophe. So scar is
14	analyze them?	14	defect healing, but scar is part of the
15	A. Usually, it is a very thin	15	physiological wound repair as well. It
16	section there and by the knives, it take the	16	depends on the quality and quantity of the
17	polymer fibers out and usually they are	17	scar.
18	they are out and you only see the cells	18	QUESTIONS BY MR. THOMAS:
19	around.	19	Q. Describe for me, please, in as
20	Q. Okay. So you actually when you	20	detail as you can, what it is about the
21	look at the slides, you're looking at a hole	21	picture on the left on page 71 that shows you
22	as opposed to the polymer?	22	that this is a scar plate?
23	A. Very often, yeah.	23	A. There is no not any or there
24	Q. Can you tell on 71 whether	24	is no area where I can identify a pore that
	Page 579		Page 581
1	you're looking at the polymer or the hole?	1	is filled by fat tissue. That is not filled
2	A. From these images, it is very	2	by scar and our definition of bridging was
3	small, but I think even if you make it	3	that the pore is completely filled by scar
4	bigger, that you don't see directly the	4	tissue.
5	polymer in this, but only the holes.	5	Q. When you say "your definition,"
6	Q. Okay. The middle slide depicts	6	that definition accepted generally in the
7	a normal fiber foreign body reaction,	7	field of pathology?
8	correct?	8	A. That is the definition that we
9	A. A typical.	9	published since years what I what is
10	Q. A typical foreign body	10	accepted by the documents from Ethicon I saw,
11	reaction.	11	I never realized that there was any objection
12	Is there anything else	12	to this.
13	remarkable about the middle slide?	13	Q. My question is: Do you know
14	A. No.	14	that the definition that you used is
15	Q. Now, the slide on the left, you	15	acceptable in the field of pathology?
16	said the red, does that depict collagen?	16	MR. ANDERSON: Objection.
17	A. Yeah. Mainly collagen and this	17	THE WITNESS: I don't know what
18	is expressing the scar reaction there.	18	is your feeling, what does it mean
19	Q. Okay.	19	acceptance in the field of pathology,
20	A. It's not the yellow color of	20	by whom, in what specific situation?
21	the fat tissue, but it's the red color of	21	QUESTIONS BY MR. THOMAS:
22	collagen-rich scar. Fibrotic.	22	Q. Okay. Let's go to the same
23	Fibroconnective tissue.	23	page on the right side, I would like for you
24	Q. So I thought collagen was good.	24	to describe for me, please, what is

61 (Pages 578 to 581)

	Page 582		Page 584
1	remarkable about the image on the right side	1	rejection of the light there.
2	of the three section on page 71?	2	It is just a what I have
3	A. This is a section where you see	3	seen there, I didn't know any literature
4	in the middle the two almost circular holes	4	making deeper studies to relate degradation
5	where it is likely that there a polymer	5	to this, but I think it is a finding that may
6	fiber has been there. You see on the left	6	offer the option to make investigations using
7	side of this image that it's a little bit not	7	this filter when you want to look at the
8	circular because you have a diagonal cutting	8	degradation of polypropylene.
9	in this area.	9	Q. Do you have an opinion to a
10	On the right-hand side, you may	10	reasonable degree of scientific certainty
11	have the impression that there may have been	11	that the image in the middle of the
12	some of the polymer fibers, but it's not	12	three-image set on page 72 is degradation?
13	clear whether it's a destruction of the	13	A. As I tried to explain, there is
14	tissue there by the cutting process, but,	14	no other information about the or
15	however, all of the tissue in between the	15	confirmation that degradation can be seen by
16	fibers it is scar.	16	this but for my from my point of view, it
17	Q. Next page, page 72 at the top,	17	is consistent with the opinion that there is
18	there are three images there and the heading	18	some structural change, but I need further
19	says, "Some areas of the polymer showed	19	confirmation by further ongoing studies to
20	considerable M homogeneity of the crystal	20	prove this, but I just want to mention this.
21	structure that can hint to a present change	21	Q. Okay. So just so I'm clear and
22	of the crystal structure."	22	I can stop asking questions about it, is it
23	What does that mean?	23	fair that you do not have an opinion to a
24	A. As I told you, we have we're	24	reasonable degree of scientific certainty
	Page 583		Page 585
1	frequently using this polarization filter	1	that the image in the middle of those three
2	because this allows us to differentiate	2	is degradation of the polypropylene mesh?
3	between collagen 1 and collagen 3 or to	3	A. Yes.
4	yeah. And to identify collagens better.	4	Q. Okay. Is the image in the
5	And another option of this	5	middle of the page of 72, is that your
6	polarization filter is the identification of	6	camera? What is that?
7	some smaller particles, and I use this to	7	A. The middle here?
8	look whether there are some particles. And	8	Q. Yes.
9	if you're looking at the upper row in the	9	A. No, it's another image of this
10	right picture, you see that there are very,	10	section where you see the different
11	very small particles there, highlighted	11	appearance of the polypropylene.
12	there. And it is usually just doing it	12	Q. I am sorry.
13	without the filter, you will not see them	13	A. Down there is a polymer which
14	because they are almost the same appearance	14	seems to be intact as I would have expected
15	as some cells. But when using the filter,	15	it, and in the middle, you see some light
16	you really see in a there is a foreign body.	16	changes of the appearance where I don't have
17	On the left, you see a polymer	17	any detailed explanation for the studies.
18	fiber as I would have expected it,	18	It's a new finding.
19	homogenously as a polymer. In the middle,	19	Q. These samples came to you fixed
20	you see that it is different. I have no	20	in formalin, correct?
21	explanation for this. The only explanation I	21	A. Yes.
22	can imagine is that there is some	22	Q. And slides were created.
23	heterogeneity or change in the crystal structure that leads to this different	23	Do you have any idea of the
24		24	extent to which the creation of the slides

62 (Pages 582 to 585)

1 could create any kinds of particles? 2 A. No. It's yes, of course, it 3 has to be or the type of fixation, the 4 type of handling can or can make some  1 section, but in contrast to the particles on the in the upper you see that there is a reaction cells around, which is very ties.		
2 A. No. It's yes, of course, it 2 particles on the in the upper 3 has to be or the type of fixation, the 4 type of handling can or can make some 4 particles on the in the upper 3 you see that there is a reaction 4 cells around, which is very ties		
3 has to be or the type of fixation, the 4 type of handling can or can make some 3 you see that there is a reaction cells around, which is very ties.	r row.	
4 type of handling can or can make some 4 cells around, which is very tie		
5 particles. 5 together to the surface of this		
6 So, therefore, in the upper 6 particle and this needs time.	So it	
7 row, where you see on the left side some very 7 is impossible that this particle		
8 small particles there, I cannot be sure 8 the result of the section and it		
9 whether this is done by the cutting, by the 9 clearly that even these particles		
10 preparation of these sections for these 10 the typical foreign body react		
11 stainings or whether it has been other 11 the foreign body giant cells at		
12 reasons. 12 inflammatory infiltrate there.	ia tile	
13 But if you're looking to the 13 QUESTIONS BY MR. THOMAS	<b>S</b> ·	
14 lower part of this, where you see a big 14 Q. What is your opinion with the state of the stat		
particle, a fragment of the fiber, there you  15 respect to the specific particle?		
16 see that you already have some surrounding 16 MR. ANDERSON: Other	er than what	
17 tissue response there and, therefore, it is 17 he just said?	i than what	
18 clear that this particle has been implanted  18 MR. THOMAS: Right.		
19 during the index operation there. 19 MR. ANDERSON: Oka	v In	
20 Q. Okay. Have you finished your 20 addition to what you just said		
21 comments and remarks about the top four 21 QUESTIONS BY MR. THOMAS		
22 images? 22 Q. Any further comments t		
23 A. Yes. 23 have about this specific particle?	nat you	
Q. Moving now to the image that 24 A. No.		
Page 587	Page	589
1 you just discussed, the single image at the 1 Q. Can you tell by looking	at	
bottom of page 72, and it says, "Around the 2 the what you've described as a		
3 separate particle, the usual tissue reaction 3 page 72 strike that.	particle on	
4 can be seen is known from the tissue reaction 4 Let's go to the next page.		
5 to polymer fibers."  5 Wait a minute. Before we do that	the tissue	
6 Do you have an opinion to a 6 reaction to the polymer on page 7		
7 reasonable degree of scientific certainty 7 of an interzone of polymorphous		
8 that this was a particle in Mrs. Lewis that  8 inflammatory cells with some cor		
9 came out with her tissue explant? 9 foreign body giant cells as a sign		
10 MR. ANDERSON: Objection to 10 inflammation, mainly located at the		
11 form. 11 the polymer."		
THE WITNESS: I've seen this in 12 Does that relate to the im	age	
the sections which I got and saw this 13 above or the next page?	<i>U</i> -	
particle in these slides there. 14 A. No, to this above.		
15 QUESTIONS BY MR. THOMAS: 15 Q. And that's what you wer	e	
16 Q. Okay. Do you have an opinion 16 discussing before about showing		
17 as to whether this particle was strike 17 inflammation evidence that that's		
18 that. 18 on for some time? Is that true?	- 66	
Do you have an opinion as to 19 A. This is the chronic foreign	gn	
20 whether this image on page 72 is actually a 20 body reaction that is ongoing life		
21 part of the polymer that was cut? 21 happens to the filaments but to the	•	
22 MR. ANDERSON: Objection. 22 as well and this is yeah.		
23 THE WITNESS: The polymer 23 Q. Page 73, the top of the p	age,	
24 always is cut when you make this 24 you have two images, the comme		

63 (Pages 586 to 589)

	Page 590		Page 592
1	"The thickness of this inflammatory	1	inflammatory infiltrate, and as we discussed
2	infiltrate is around 50 microns, but in some	2	yesterday, it is a wide field to identify
3	areas with close distance between the	3	which cells are specifically there. Usually
4	filaments, the entire space completely is	4	there's about 40 percent that are positive
5	filled out by this inflammatory infiltrate.	5	for markers that represent macrophages.
6	In some areas, the accumulation of	6	There are 30, 40 percent positive for markers
7	inflammatory cells indicates a more active,	7	that are related to lymphocytes as the main
8	acute inflammatory reaction."	8	cells, but what's the name is specifically,
9	Tell me what it is about those	9	we're still working on it.
10	slides that demonstrate that the entire space	10	Q. But the presence of the
11	is filled out by this inflammatory	11	inflammatory infiltrate itself is normal; is
12	infiltrate.	12	that correct?
13	A. The fact that the entire space	13	A. Normal as it is in principle,
14	between the filaments is completely filled	14	as it is compulsory of every foreign body
15	out by this infiltrate is not reflected in	15	reaction.
16	these two images.	16	Q. What is abnormal about
17	Q. Okay. What is depicted in	17	MR. ANDERSON: Hold on.
18	these images?	18	QUESTIONS BY MR. THOMAS:
19	A. You see on the left, you see	19	Q. Did I interrupt you? I didn't
20	that I tried to measure the wall, the	20	mean to.
21	yeah, the inflammatory infiltrate, the	21	A. In quantity, in quality, that
22	thickness of the inflammatory infiltrate very	22	there is it, it is normal. If you mean is it
23	close to the fiber and measured a distance of	23	normal in quantity, yeah. For heavy-weight,
24	about 50 microns here.	24	for a polypropylene, it is quantity that we
	Page 591		Page 593
1	On the left side close to the	1	can expect.
2	polymer, you see some foreign body giant	2	If you have other polymers, you
3	cells in the red in the right picture	3	won't expect so much.
4	Q. Let's stop on the left for a	4	Q. Okay. What is it about the
5	second.	5	nature of the inflammatory infiltrate that
6	How many foreign body giant	6	you see at the top of page 73 creates a risk
7	cells do you see?	7	of complications to Ms. Lewis?
8	A. I didn't count them.	8	A. The inflammatory infiltrate
9	Q. How do you determine what they	9	reflects an area of increased tissue
10	are?	10	remodelling. So you have an increased number
11	A. They are cells that that has	11	of cell dying there in you have an
12	confluent nucleus, more than one nucleus, and	12	increased turnover, you have an increased
13	you have to go to the microscope and have to	13	proliferation of these cells there because
14	go through the depth to identify whether it's	14	these inflammatory infiltrate has a more
15	a giant cell, yes or not. Otherwise, it can	15	rapid turnover than a than other tissues.
16	be single cells laying over another.	16	Q. Is what you see
17	Q. You've used the term	17	A. And, sorry
18	"inflammatory infiltrate."	18	Q. I apologize.
19	What is included in	19	A. And, therefore, the presence of
20	inflammatory infiltrate?	20	an inflammatory infiltrate, that means that
21	A. The inflammatory infiltrate, it	21	there is a chronic wound, means an
22	can be best seen on the right side where you	22	intensified cell turnover with possible late
23	see a lot of these blue nucleus of these	23	risks, but and an increased risk for
24	cells. These cells indicate this	24	migration of the implant.

64 (Pages 590 to 593)

	Page 594		Page 596
1	QUESTIONS BY MR. THOMAS:	1	you mean plane?
2	Q. There was no evidence in the	2	THE WITNESS: A plane, yeah.
3	Carolyn Lewis case that there was a migration	3	QUESTIONS BY MR. THOMAS:
4	of the implant, was there?	4	Q. So is it fair to understand
5	MR. ANDERSON: Objection.	5	that it's your opinion that your microscopic
6	THE WITNESS: I cannot state	6	review of these slides shows you that there
7	this from these sections.	7	was folding demonstrated, but this slide
8	QUESTIONS BY MR. THOMAS:	8	that's in the middle, this image that's in
9	Q. Okay.	9	the middle of page 73 does not show that?
10	A. It's impossible.	10	A. That is that is correct.
11	Q. Can you state that from your	11	Q. And you need to see the entire
12	review of the medical records in the case?	12	field in order to understand what you believe
13	Do you know that?	13	to be folding demonstrated by that slide?
14		14	A. That is correct.
15	A. Whether it was a real migration?	15	Q. Is the rest of the action
16	<del>-</del>	16	
17	Q. Yes. A. Of this? No.	17	excuse me.
18			Is the rest of the reaction in
19	Q. Okay. Are the findings that	18 19	the middle of page 73 that you've described
20	you've described in response to my questions	l .	consistent with the foreign body reaction to
	concerning the images at the top of page 23	20	every heavy-weight, small pore mesh?
21	consistent with the reaction that any	21	A. Yes.
22	polypropylene mesh would have?	22	Q. It is?
23	A. With any heavy-weight, small	23	A. Yes.
24	pore polypropylene meshes, they're completely	24	Q. Thank you.
	Page 595		Page 597
1	consistent.	1	MR. ANDERSON: He was waiting
2	Q. Okay. Middle of page 73, what	2	to make sure you distinguish
3	do we see?	3	heavy-weight, small pore. That's why
4	A. We see, again, the holes where	4	he was smiling.
5	the polymers has been. You see an	5	QUESTIONS BY MR. THOMAS:
6	inflammatory infiltrate around it and it	6	Q. Page 73, the lower image, what
7	is it is an area where a folding and	7	does the lower image depict?
8	doubling of the layers can be seen, but not	8	A. This is an image, I believe,
9	in this image, unfortunately, because we are	9	that the the expression of folding is
10	limited with the lowest magnification is	10	related to the lower image there. There you
11	40, and, therefore, it is impossible to get a	11	have the magnification of 40 and there you
12	good overview. To really either no,	12	have a wider view of the meshes. And but in
13	except of looking at the slides with a	13	reality when you look to the section, you see
14	microscope where you can see that the	14	further on where the mesh is going to. Here
15	configuration of the meshes are not in a	15	you have you see several places where the
16	plane area any longer, the alternative would	16	polymer has been this is hardly to believe
17	be to make five, six images and to place them	17	that this is the mesh with the in plane
18	together.	18	area without doubling or folding that you get
19	As we made it, we have seen it	19	this section here.
20	already in some of the old documents where we	20	Q. And help me, I am sorry, it's
21	made these long combination of various	21	either late in the day or I'm not very smart,
22	pictures to see the configuration of the	22	maybe both. The white areas in those, are
23	meshes.	23	those actual polymers?
24	MR. ANDERSON: You said plane,	24	A. These are some of the few parts

65 (Pages 594 to 597)

	Page 598		Page 600
1	where the polymers are still in place. The	1	A. Not for me, but there are
2	others you only see the holes, but, of	2	people who are for whom this is an
3	course, there has been some polymers now	3	important message.
4	laying in between or being removed by the	4	Q. In the slides that you analyzed
5	knife.	5	for Ms. Lewis, did you find any evidence of a
6	Q. So in order for you to conclude	6	neuroma?
7	that there's been folding here, you count	7	A. No.
8	both the polymers that you see and the holes	8	Q. Did you find any evidence of
9	where you suggest that polymers have been and	9	infection?
10	conclude from that that there had to be	10	A. If I remember correctly, there
11	folding?	11	was an area where you have an enhanced or
12	A. Yes.	12	where you have an intensified inflammatory
13	Q. Anything more than that that	13	infiltrate in this field. I know from
14	supports your contention that there's	14	Professor Klosterhalfen that the definition
15	folding?	15	of infection sometimes is only the appearance
16	A. No. It is the appearance of	16	of some more inflammatory cells than usually
17	the holes where the polymers has been and the	17	so, therefore, I cannot state it for sure
18	geometrical configuration of these in a	18	that there has been one.
19	section.	19	Q. Do you have an opinion to a
20	Q. Is there anything else	20	reasonable degree of scientific certainty
21	remarkable about the lower slide on page 73	21	based on your review of the slides that's
22	other than your testimony about the folding?	22	been provided to you that Ms. Lewis has an
23	A. No.	23	infection because of her mesh?
24	Q. Is the foreign body reaction	24	A. I don't have sure proof that
	Page 599		Page 601
1	depicted in the lower slide on page 73	1	there was an infection.
2	consistent with heavy-weight, small pore	2	Q. So is it fair to understand you
3	meshes?	3	don't have such an opinion?
4	A. Yes.	4	A. Have an opinion that I did not
5	Q. On page 73 at the top, what do	5	see it.
6	we see?	6	Q. Great.
7	A. This is an S100 staining and in	7	MR. THOMAS: Can we take a
8	the little of the left part of the image,	8	break, please?
9	there I expect there has been a polymer. It	9	(Off the record at 3:54 p.m.)
10	was removed by the preparation, and you have	10	QUESTIONS BY MR. THÔMAS:
11	some areas with a brown staining there and	11	Q. Doctor, I want to direct your
12	this is consistent with the presence of a	12	attention to the chart that appears at the
13	nerve in the area.	13	end of your report where you compile your
14	As we have three sections which	14	findings from the your review of the
15	are very close to each other, if you're	15	slides and the spreadsheet has columns O, P,
16	looking to all three sections with \$100, you	16	Q, R where you record what you found from
17	see that it's not an artifact an	17	your review of the slides.
18	artificial staining in one slide, but it is	18	Is that correct?
19	an ongoing structure going through all of	19	A. That is correct.
20	these three slides so that I have no doubts	20	Q. The first column P says
21	that there's a small nerve.	21	bridging, 1, less than 5 percent; 2, 5 to
22	Q. Okay. And as we said before,	22	30 percent; 3, 30 to 80 percent; and 4,
	· · · · · · · · · · · · · · · · · · ·		
23 24	the mere presence of a nerve is not remarkable by itself?	23 24	greater than 80 percent.  How did you measure that?

66 (Pages 598 to 601)

1	Page 602		Page 604
	A. If you look to the entire	1	in scar tissue as well. So it means that you
2	section, you have some areas where you can	2	have scar and scar is mainly consistent with
3	identify something like a pore because you	3	collagen leading to wound or being
4	see some filament on the one side and on the	4	major majorly important for the wound
5	other side. And if you look to the space in	5	contraction and some fibroblasts there and,
6	between two adjacent filaments, then you can	6	of course, vessels. The only area where you
7	assume this to be a pore. And if this is	7	hardly have vessels is very, very close to
8	filled, if the area between the two	8	the polymer fiber.
9	neighboring filaments, if this is filled by	9	But the appearance of vessels
10	fat tissue, I notice this in this chart and I	10	is no indicator of scar plate or scar net
11	only saw one or two times in all these	11	or
12	sections that I got the image where I saw two	12	Q. Do you know whether this
13	filaments and the space in between was not	13	scaling that you've done for the bridging is
14	filled by scar tissue.	14	a method that's generally accepted by
15	So if I code this with more	15	pathologists to look at mesh explants?
16	than 80 percent, then you got in all these	16	A. I made this scaling just for
17	sections four.	17	these cases to give to be able to give an
18	Q. Is 80 percent consistent with	18	impression of what I've seen there.
19	what you've described as scar plate	19	Q. What is the significance in
20	formation?	20	your judgment of scaling of less than 5
21	A. Scar plate formation has been a	21	percent? Excuse me, strike that.
22	term in a specific period of time. I think	22	What is what is the
23	it's consistent.	23	significance in your judgment of bridging
24	Q. Okay. Well, do you use a	24	less than 5 percent?
	Page 603		Page 605
1	different term now to describe what you find	1	A. You have to understand what we
2	when you find bridging at greater than	2	third in those 15, 20 years is not only to
3	80 percent?		tried in these 15, 20 years is not only to
	- · F	3	make a qualitative description of the tissue
4	A. You have to be very careful	4	make a qualitative description of the tissue reaction but to find some quantitative an
4 5	A. You have to be very careful when using the term "scar plate" because some	4 5	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there.
4 5 6	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically	4 5 6	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there.  And this is very difficult because from the
4 5 6 7	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the	4 5 6 7	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there.  And this is very difficult because from the methods. So, therefore, we make we
4 5 6 7 8	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made	4 5 6 7 8	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when
4 5 6 7 8 9	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have	4 5 6 7 8 9	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming
4 5 6 7 8 9	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what	4 5 6 7 8 9	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than
4 5 6 7 8 9 10	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.	4 5 6 7 8 9 10	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a
4 5 6 7 8 9 10 11 12	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.  Overall, this is completely in	4 5 6 7 8 9 10 11 12	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.
4 5 6 7 8 9 10 11 12	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.  Overall, this is completely in accordance what we expect that we have	4 5 6 7 8 9 10 11 12 13	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.  Q. Why do you use 5 to 10 percent
4 5 6 7 8 9 10 11 12 13 14	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.  Overall, this is completely in accordance what we expect that we have predominantly bridged or this these pores	4 5 6 7 8 9 10 11 12 13 14	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.  Q. Why do you use 5 to 10 percent as your next range?
4 5 6 7 8 9 10 11 12 13 14 15	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.  Overall, this is completely in accordance what we expect that we have predominantly bridged or this these pores filled by scar tissue, yeah.	4 5 6 7 8 9 10 11 12 13 14 15	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.  Q. Why do you use 5 to 10 percent as your next range?  A. It is for scientific reasons
4 5 6 7 8 9 10 11 12 13 14 15 16	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.  Overall, this is completely in accordance what we expect that we have predominantly bridged or this these pores filled by scar tissue, yeah.  MR. ANDERSON: So the first one	4 5 6 7 8 9 10 11 12 13 14 15 16	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.  Q. Why do you use 5 to 10 percent as your next range?  A. It is for scientific reasons you should have at least four different
4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.  Overall, this is completely in accordance what we expect that we have predominantly bridged or this these pores filled by scar tissue, yeah.  MR. ANDERSON: So the first one was macroscopically and then you said	4 5 6 7 8 9 10 11 12 13 14 15 16 17	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there.  And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.  Q. Why do you use 5 to 10 percent as your next range?  A. It is for scientific reasons you should have at least four different scoring levels, otherwise, you very likely go
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.  Overall, this is completely in accordance what we expect that we have predominantly bridged or this these pores filled by scar tissue, yeah.  MR. ANDERSON: So the first one was macroscopically and then you said microscopically.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.  Q. Why do you use 5 to 10 percent as your next range?  A. It is for scientific reasons you should have at least four different scoring levels, otherwise, you very likely go to the middle and then you will not see any
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.  Overall, this is completely in accordance what we expect that we have predominantly bridged or this these pores filled by scar tissue, yeah.  MR. ANDERSON: So the first one was macroscopically and then you said microscopically.  THE WITNESS: Microscopically.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.  Q. Why do you use 5 to 10 percent as your next range?  A. It is for scientific reasons you should have at least four different scoring levels, otherwise, you very likely go to the middle and then you will not see any difference so you need at least four
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.  Overall, this is completely in accordance what we expect that we have predominantly bridged or this these pores filled by scar tissue, yeah.  MR. ANDERSON: So the first one was macroscopically and then you said microscopically.  THE WITNESS: Microscopically.  QUESTIONS BY MR. THOMAS:	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.  Q. Why do you use 5 to 10 percent as your next range?  A. It is for scientific reasons you should have at least four different scoring levels, otherwise, you very likely go to the middle and then you will not see any difference so you need at least four different levels and you have to start from
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.  Overall, this is completely in accordance what we expect that we have predominantly bridged or this these pores filled by scar tissue, yeah.  MR. ANDERSON: So the first one was macroscopically and then you said microscopically.  THE WITNESS: Microscopically.  QUESTIONS BY MR. THOMAS:  Q. So when you say 80 percent	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.  Q. Why do you use 5 to 10 percent as your next range?  A. It is for scientific reasons you should have at least four different scoring levels, otherwise, you very likely go to the middle and then you will not see any difference so you need at least four different levels and you have to start from the extremes always and none and then you
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.  Overall, this is completely in accordance what we expect that we have predominantly bridged or this these pores filled by scar tissue, yeah.  MR. ANDERSON: So the first one was macroscopically and then you said microscopically.  THE WITNESS: Microscopically.  QUESTIONS BY MR. THOMAS:  Q. So when you say 80 percent filled with scar, does that mean that there	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.  Q. Why do you use 5 to 10 percent as your next range?  A. It is for scientific reasons you should have at least four different scoring levels, otherwise, you very likely go to the middle and then you will not see any difference so you need at least four different levels and you have to start from the extremes always and none and then you have to fill in between. I have no problem
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.  Overall, this is completely in accordance what we expect that we have predominantly bridged or this these pores filled by scar tissue, yeah.  MR. ANDERSON: So the first one was macroscopically and then you said microscopically.  THE WITNESS: Microscopically.  QUESTIONS BY MR. THOMAS:  Q. So when you say 80 percent	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	make a qualitative description of the tissue reaction but to find some quantitative an or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make we introduced there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.  Q. Why do you use 5 to 10 percent as your next range?  A. It is for scientific reasons you should have at least four different scoring levels, otherwise, you very likely go to the middle and then you will not see any difference so you need at least four different levels and you have to start from the extremes always and none and then you

67 (Pages 602 to 605)

1 I was bound to this. 2 Q. Have you ever used this type of 3 coding before in analyzing mesh explants? 4 A. We used such a type of coding 5 very, very often to give a semi-quantitative 6 analysis of our staining, yeah. 7 Q. When you say "we," who do you 8 mean? 9 A. I, in my projects where we 10 analyze these tissue samples, that is a major 11 aspect before we starting the analysis to 12 define the parameters and to define the 13 coding, how to make the readout there. 14 Q. Okay. Do you always use the 15 same numbers? 16 A. No. It varies from the 17 specific question there, but it is about four 18 to five. 19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it, 22 correct?  1 if you identified shrinkage of 20 percent, 2 would that be a positive finding in your 2 would that be a positive finding in your 2 dentr? 4 A. I didn't measure the degree of 3 shrinkage. It was not possible to do so. It 4 was just a configuration of the mesh. 6 was just a configuration of the mesh. 7 Q. So if you saw any shrinkage at all, it would be a positive finding in your 2 dentr?  A. I didn't measure the degree of 3 shrinkage. It was not possible to do so. It 4 was just a configuration of the mesh. 6 was just a configuration of the mesh. 7 Q. So if you saw any shrinkage at all, it would be a positive finding? 9 A. If I had the impression that 10 the configuration of the mesh changes by 11 pushing together, going to waves or by 12 doubling, these are the two different things 13 that indicates either shrinkage, pushing it 14 together, or folding 15 Q. The only reason I'm asking, 16 Doctor, is because I thought we decided that 17 all wounds shrink to some extent, generally 18 at least 20 percent. 19 A. If I had the impression that 10 the configuration of the mesh. 10 the configuration of the mesh. 11 to colling of the mesh changes by 12 doubling, these are the two different things 13 that indicates either shrinkage, pushing it 14 together, or folding 15 and I wounds shrin	
2 Q. Have you ever used this type of 3 coding before in analyzing mesh explants? 4 A. We used such a type of coding 5 very, very often to give a semi-quantitative 6 analysis of our staining, yeah. 7 Q. When you say "we," who do you 8 mean? 9 A. I, in my projects where we 10 analyze these tissue samples, that is a major 11 aspect before we starting the analysis to 12 define the parameters and to define the 13 coding, how to make the readout there. 14 Q. Okay. Do you always use the 15 same numbers? 16 A. No. It varies from the 17 specific question there, but it is about four 18 to five. 19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it, 2 would that be a positive finding in your 3 chart? 4 A. I didn't measure the degree of 5 shrinkage. It was not possible to do so. It 6 was just a configuration of the mesh. 7 Q. So if you saw any shrinkage at all, it would be a positive finding? 9 A. If I had the impression that 10 the configuration of the mesh changes by 11 pushing together, going to waves or by 12 doubling, these are the two different things 13 that indicates either shrinkage, pushing it 14 together, or folding 15 Q. The only reason I'm asking, 16 Doctor, is because I thought we decided that 17 all wounds shrink to some extent, generally 18 to five. 19 And so as I understood your 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it, 22 testimony earlier, that means that every mesh 21 explanted would be a positive finding here.	
3 coding before in analyzing mesh explants? 4 A. We used such a type of coding 5 very, very often to give a semi-quantitative 6 analysis of our staining, yeah. 7 Q. When you say "we," who do you 8 mean? 9 A. I, in my projects where we 10 analyze these tissue samples, that is a major 11 aspect before we starting the analysis to 12 define the parameters and to define the 13 coding, how to make the readout there. 14 Q. Okay. Do you always use the 15 same numbers? 16 A. No. It varies from the 17 specific question there, but it is about four 18 to five. 19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it, 2 defined the parameters and to define the analysis to 2 coding, how to make the readout there. 2 defined the parameters and to define the analysis to 3 chart? 4 A. I didn't measure the degree of shrinkage. It was not possible to do so. It was possible to do so. It was not possible to do so. It was postive finding?  A. I didn't measure the degree of shrinkage. It was not possible to do so. It was just a configuration of the mesh.  A. I didn't measure the degree of shrinkage. It was not possible to do so. It was positive finding?  A. I fl had the impression that the configuration of the mesh.  10 the configuration of the mesh.  11 pushing together, going to waves or by doubling, these are the two different things that indicates either shrinkage, pushing it together, or folding  12 together, or folding  13 that indicates either shrinkage, pushing it together, or folding  14 together, or folding  15 Doctor, is because I thought we decided that all wounds shrink to some extent, generally at least 20 percent.  19 A. Al I didn't measure the degree of shrinkage, vin the shrinkage.  20 the configuration of the mesh.  21 Least 20 percent.  22 Ex	
A. We used such a type of coding very, very often to give a semi-quantitative analysis of our staining, yeah.  Q. When you say "we," who do you mean?  A. I, in my projects where we analyze these tissue samples, that is a major aspect before we starting the analysis to define the parameters and to define the coding, how to make the readout there.  Q. Okay. Do you always use the same numbers?  A. No. It varies from the cofive.  Q. Okay. Under folding or collaboration of the mesh. A. I didn't measure the degree of shrinkage. It was not possible to do so. It was just a configuration of the mesh.  A. If I had the impression that the configuration of the mesh changes by all, it would be a positive finding?  A. If I had the impression that the configuration of the mesh changes by all, it would be a positive finding?  A. If I had the impression that the configuration of the mesh.  10 the configuration of the mesh. 11 pushing together, going to waves or by 12 doubling, these are the two different things 13 that indicates either shrinkage, pushing it 14 together, or folding 15 Q. The only reason I'm asking, 16 Doctor, is because I thought we decided that 17 all wounds shrink to some extent, generally 18 to five. 19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it, 21 explanted would be a positive finding here.	
5 very, very often to give a semi-quantitative 6 analysis of our staining, yeah. 7 Q. When you say "we," who do you 8 mean? 9 A. I, in my projects where we 10 analyze these tissue samples, that is a major 11 aspect before we starting the analysis to 12 define the parameters and to define the 13 coding, how to make the readout there. 14 Q. Okay. Do you always use the 15 same numbers? 16 A. No. It varies from the 17 specific question there, but it is about four 18 to five. 19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it, 22 so if you saw any shrinkage at all, it would be a positive finding? 2 A. If I had the impression that the configuration of the mesh changes by 10 the configuration of the mesh changes by 11 pushing together, going to waves or by 12 doubling, these are the two different things 13 that indicates either shrinkage, pushing it 14 together, or folding 15 Q. The only reason I'm asking, 16 Doctor, is because I thought we decided that 17 all wounds shrink to some extent, generally 18 at least 20 percent. 19 And so as I understood your 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it, 22 explanted would be a positive finding here.	
6 analysis of our staining, yeah. 7 Q. When you say "we," who do you 8 mean? 9 A. I, in my projects where we 10 analyze these tissue samples, that is a major 11 aspect before we starting the analysis to 12 define the parameters and to define the 13 coding, how to make the readout there. 14 Q. Okay. Do you always use the 15 same numbers? 16 A. No. It varies from the 17 specific question there, but it is about four 18 to five. 19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it, 2	
7Q. When you say "we," who do you7Q. So if you saw any shrinkage at8mean?8all, it would be a positive finding?9A. I, in my projects where we9A. If I had the impression that10analyze these tissue samples, that is a major10the configuration of the mesh changes by11aspect before we starting the analysis to11pushing together, going to waves or by12define the parameters and to define the12doubling, these are the two different things13coding, how to make the readout there.13that indicates either shrinkage, pushing it14Q. Okay. Do you always use the14together, or folding15Same numbers?15Q. The only reason I'm asking,16A. No. It varies from the16Doctor, is because I thought we decided that17specific question there, but it is about four17all wounds shrink to some extent, generally18to five.18at least 20 percent.19Q. Okay. Under folding or19And so as I understood your20shrinkage, that's "or," so if it's either20testimony earlier, that means that every mesh21folding or shrinkage, you capture it,21explanted would be a positive finding here.	
8 mean? 9 A. I, in my projects where we 10 analyze these tissue samples, that is a major 11 aspect before we starting the analysis to 12 define the parameters and to define the 13 coding, how to make the readout there. 14 Q. Okay. Do you always use the 15 same numbers? 16 A. No. It varies from the 17 specific question there, but it is about four 18 to five. 19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it, 20 A. If I had the impression that 10 the configuration of the mesh changes by 11 pushing together, going to waves or by 12 doubling, these are the two different things 13 that indicates either shrinkage, pushing it 14 together, or folding 15 Q. The only reason I'm asking, 16 Doctor, is because I thought we decided that 17 all wounds shrink to some extent, generally 18 at least 20 percent. 19 And so as I understood your 20 testimony earlier, that means that every mesh 21 folding or shrinkage, you capture it, 21 explanted would be a positive finding here.	
9 A. I, in my projects where we 10 analyze these tissue samples, that is a major 11 aspect before we starting the analysis to 12 define the parameters and to define the 13 coding, how to make the readout there. 14 Q. Okay. Do you always use the 15 same numbers? 15 Q. The only reason I'm asking, 16 A. No. It varies from the 17 specific question there, but it is about four 18 to five. 19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it, 20 the configuration of the mesh changes by 10 the configuration of the mesh changes by 11 pushing together, going to waves or by 12 doubling, these are the two different things 13 that indicates either shrinkage, pushing it 14 together, or folding 15 Q. The only reason I'm asking, 16 Doctor, is because I thought we decided that 17 all wounds shrink to some extent, generally 18 at least 20 percent. 19 And so as I understood your 20 testimony earlier, that means that every mesh 21 folding or shrinkage, you capture it, 21 explanted would be a positive finding here.	
10 analyze these tissue samples, that is a major 11 aspect before we starting the analysis to 12 define the parameters and to define the 13 coding, how to make the readout there. 14 Q. Okay. Do you always use the 15 same numbers? 16 A. No. It varies from the 17 specific question there, but it is about four 18 to five. 19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it,  10 the configuration of the mesh changes by 11 pushing together, going to waves or by 12 doubling, these are the two different things 13 that indicates either shrinkage, pushing it 14 together, or folding 15 Q. The only reason I'm asking, 16 Doctor, is because I thought we decided that 17 all wounds shrink to some extent, generally 18 at least 20 percent. 19 And so as I understood your 20 testimony earlier, that means that every mesh 21 folding or shrinkage, you capture it, 21 explanted would be a positive finding here.	
aspect before we starting the analysis to define the parameters and to define the coding, how to make the readout there.  Q. Okay. Do you always use the same numbers?  A. No. It varies from the specific question there, but it is about four to five.  Q. Okay. Under folding or shrinkage, that's "or," so if it's either folding or shrinkage, you capture it,  11 pushing together, going to waves or by doubling, these are the two different things that indicates either shrinkage, pushing it together, or folding 15 Q. The only reason I'm asking, Doctor, is because I thought we decided that all wounds shrink to some extent, generally at least 20 percent.  19 And so as I understood your 20 testimony earlier, that means that every mesh 21 explanted would be a positive finding here.	
define the parameters and to define the coding, how to make the readout there.  Q. Okay. Do you always use the same numbers?  A. No. It varies from the specific question there, but it is about four to five.  Q. Okay. Under folding or shrinkage, that's "or," so if it's either  folding or shrinkage, you capture it,  12 doubling, these are the two different things that indicates either shrinkage, pushing it together, or folding 15 Q. The only reason I'm asking, 16 Doctor, is because I thought we decided that 17 all wounds shrink to some extent, generally 18 at least 20 percent. 19 And so as I understood your 20 testimony earlier, that means that every mesh 21 explanted would be a positive finding here.	
coding, how to make the readout there.  Q. Okay. Do you always use the same numbers?  A. No. It varies from the specific question there, but it is about four to five.  Q. Okay. Under folding or shrinkage, that's "or," so if it's either folding or shrinkage, you capture it,  13 that indicates either shrinkage, pushing it together, or folding  14 together, or folding  15 Q. The only reason I'm asking,  16 Doctor, is because I thought we decided that all wounds shrink to some extent, generally at least 20 percent.  19 And so as I understood your testimony earlier, that means that every mesh explanted would be a positive finding here.	
Q. Okay. Do you always use the 15 same numbers? 16 A. No. It varies from the 17 specific question there, but it is about four 18 to five. 19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it,  14 together, or folding 15 Q. The only reason I'm asking, 16 Doctor, is because I thought we decided that 17 all wounds shrink to some extent, generally 18 at least 20 percent. 19 And so as I understood your 20 testimony earlier, that means that every mesh 21 explanted would be a positive finding here.	
15 same numbers?  16 A. No. It varies from the 17 specific question there, but it is about four 18 to five. 19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it,  15 Q. The only reason I'm asking, 16 Doctor, is because I thought we decided that 17 all wounds shrink to some extent, generally 18 at least 20 percent. 19 And so as I understood your 20 testimony earlier, that means that every mesh 21 explanted would be a positive finding here.	
A. No. It varies from the specific question there, but it is about four to five.  16 Doctor, is because I thought we decided that 17 all wounds shrink to some extent, generally 18 at least 20 percent.  19 Q. Okay. Under folding or 19 And so as I understood your 20 shrinkage, that's "or," so if it's either 20 testimony earlier, that means that every mesh 21 folding or shrinkage, you capture it, 21 explanted would be a positive finding here.	
17specific question there, but it is about four17all wounds shrink to some extent, generally18to five.18at least 20 percent.19Q. Okay. Under folding or19And so as I understood your20shrinkage, that's "or," so if it's either20testimony earlier, that means that every mesh21folding or shrinkage, you capture it,21explanted would be a positive finding here.	
18 to five. 19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it,  18 at least 20 percent. 19 And so as I understood your 20 testimony earlier, that means that every mesh 21 explanted would be a positive finding here.	
19 Q. Okay. Under folding or 20 shrinkage, that's "or," so if it's either 21 folding or shrinkage, you capture it,  19 And so as I understood your 20 testimony earlier, that means that every mesh 21 explanted would be a positive finding here.	- 1
shrinkage, that's "or," so if it's either folding or shrinkage, you capture it, 20 testimony earlier, that means that every mesh explanted would be a positive finding here.	- 1
21 folding or shrinkage, you capture it, 21 explanted would be a positive finding here.	
LAA COUECL! LAA A MOHA II HIMA DE HAA MIN IMIN IMIN IMIN IMIN IMIN IMIN IMI	
23 A. Yes. 23 I call it shrinkage. I should have named it	
24 Q. Didn't we decide that every 24 waving form or deformation of the shape due	
Page 607 Page	09
1 mesh is going to fold excuse me, didn't we 1 to shrinkage.	
2 decide that every mesh is going to shrink 2 Q. Okay. The last category,	
3 approximately 20 percent? 3 "Nerve contact within one millimeter of	
4 A. What I have been thinking of 4 sling."	
5 when looking for this folding was a 5 Have we do we agree that	
6 double-layer structure which I cannot explain 6 there's nothing remarkable about nerve	
7 by the video I saw where the sling is 7 contact in itself? The nerves are going to	
8 implanted in a plane area, but when you have 8 be	
9 the impression that you have two or three 9 A. The fact that there are nerves	
layers of mesh materials on top of each 10 in this place is not remarkable. The fact	
other, I would say that there's a folding.  11 that these nerves are laying in this scar	
12 And shrinkage is if you have a 12 tissue gives a good explanation why some	
13 configuration as a with a folding there in 13 patients have chronic pain.	
this area.  14 Q. Okay. And if PVDF mesh is	
15 Q. So this says "folding or 15 placed for the treatment of stress urinary	
16 shrinkage."  16 incontinence and comes in contact with a	
17 A. Yeah. 17 nerve, you would have the same risk of	
18 Q. If you found shrinkage of 18 chronic pain, correct?	
19 20 percent, would that be a positive finding? 19 MR. ANDERSON: Objection.	
20 A. This is a description of what 20 Go ahead.	
21 can be seen there. What is the appearance 21 THE WITNESS: I would assume	
22 of 22 that if the nerve is laying in the	
23 Q. I understand that. 23 fields of scar that is close to PVDF	
What I'm trying to understand 24 slings that there will be the chance	

68 (Pages 606 to 609)

	Page 610		Page 612
1	for chronic pain as well.	1	a slide, that's the only thing I can
2	However, the overall chance to	2	think of. If that makes sense.
3	get entrapped into scar tissue, I	3	MR. THOMAS: I just want to
4	would expect is much lower and,	4	make sure I haven't missed something
5	therefore, the risk for pain is much	5	in his report in the information that
6	lower when using large pore PVDF	6	you provided to me here that I need to
7	structures.	7	explore.
8	QUESTIONS BY MR. THOMAS:	8	MR. ANDERSON: Anything
9	Q. But we don't know that until we	9	significant.
10	study it, correct?	10	MR. THOMAS: Either you or the
11	A. We note from all our	11	doctor can tell me, if there's
12	experience, from all our work that the risk	12	something else I need to explore, I
13	for chronic pain decreases by using large	13	want to do it, otherwise, I'm about to
14	pore structures and decreasing the amount of	14	quit.
15	inflammatory reaction, yes, we know it	15	MR. ANDERSON: I think he's
16	already.	16	listed in his report in the grid and I
17	Q. From animal studies?	17	think you've covered most all of that
18	A. No. From clinical studies as	18	for her and I don't know if you
19	well. We can go back to the guidelines where	19	covered all of the path slides that
20	it is favored, the advantage of large pore	20	are in the back or not.
21	meshes because of less chronic pain.	21	MR. THOMAS: Well, that's the
22	Q. Have we covered all of your	22	problem is I don't know which ones are
23	opinions with respect to Carolyn Lewis?	23	hers.
24	MR. ANDERSON: Objection.	24	MR. ANDERSON: Yeah, you do.
	Page 611		Page 613
1	THE WITNESS: I have the	1	The grid says 13-23 and then the
2	impression that we covered a lot.	2	images correspond. That's one of the
3	There are	3	
			reasons I gave that to you to try to
4	OUESTIONS BY MR. THOMAS:	4	reasons I gave that to you to try to make that a little easier.
4 5	QUESTIONS BY MR. THOMAS: Q. I'm talking about Carolyn Lewis	1	make that a little easier.
4 5 6	Q. I'm talking about Carolyn Lewis	4	make that a little easier. MR. THOMAS: Thank you.
5		4 5	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?
5 6	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did. Have we covered it all?	4 5 6	make that a little easier. MR. THOMAS: Thank you.
5 6 7	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did. Have we covered it all? MR. ANDERSON: Objection. With	4 5 6 7	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this
5 6 7 8	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did. Have we covered it all?	4 5 6 7 8	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in
5 6 7 8 9	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did. Have we covered it all? MR. ANDERSON: Objection. With "whether you've covered it all." MR. THOMAS: Well, I'm trying	4 5 6 7 8 9	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.
5 6 7 8 9	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did. Have we covered it all? MR. ANDERSON: Objection. With "whether you've covered it all."	4 5 6 7 8 9	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.  MR. THOMAS: They're not. No.
5 6 7 8 9 10	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did. Have we covered it all? MR. ANDERSON: Objection. With "whether you've covered it all." MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think	4 5 6 7 8 9 10	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.  MR. THOMAS: They're not. No.  MR. ANDERSON: They're grouped
5 6 7 8 9 10 11	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did. Have we covered it all? MR. ANDERSON: Objection. With "whether you've covered it all." MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think I've covered every sentence in the	4 5 6 7 8 9 10 11	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.  MR. THOMAS: They're not. No.  MR. ANDERSON: They're grouped together.
5 6 7 8 9 10 11 12	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did. Have we covered it all? MR. ANDERSON: Objection. With "whether you've covered it all." MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think I've covered every sentence in the report that deals with the mesh. If	4 5 6 7 8 9 10 11 12 13	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.  MR. THOMAS: They're not. No.  MR. ANDERSON: They're grouped together.  MR. THOMAS: Okay.
5 6 7 8 9 10 11 12 13	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did.  Have we covered it all?  MR. ANDERSON: Objection. With "whether you've covered it all."  MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think I've covered every sentence in the report that deals with the mesh. If there's something that's in the report	4 5 6 7 8 9 10 11 12 13 14	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.  MR. THOMAS: They're not. No.  MR. ANDERSON: They're grouped together.  MR. THOMAS: Okay.  MR. ANDERSON: There we go. If
5 6 7 8 9 10 11 12 13 14 15	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did.  Have we covered it all?  MR. ANDERSON: Objection. With "whether you've covered it all."  MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think I've covered every sentence in the report that deals with the mesh. If there's something that's in the report that I don't know about  MR. ANDERSON: The only issue, Dave, is that he said that a lot of	4 5 6 7 8 9 10 11 12 13 14 15	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.  MR. THOMAS: They're not. No.  MR. ANDERSON: They're grouped together.  MR. THOMAS: Okay.  MR. ANDERSON: There we go. If you find the dark ones, it makes it
5 6 7 8 9 10 11 12 13 14 15 16	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did.  Have we covered it all?  MR. ANDERSON: Objection. With "whether you've covered it all."  MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think I've covered every sentence in the report that deals with the mesh. If there's something that's in the report that I don't know about  MR. ANDERSON: The only issue,	4 5 6 7 8 9 10 11 12 13 14 15	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.  MR. THOMAS: They're not. No.  MR. ANDERSON: They're grouped together.  MR. THOMAS: Okay.  MR. ANDERSON: There we go. If you find the dark ones, it makes it easier.  MR. THOMAS: The first one that I have here appears to be and
5 6 7 8 9 10 11 12 13 14 15 16 17	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did.  Have we covered it all?  MR. ANDERSON: Objection. With "whether you've covered it all."  MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think I've covered every sentence in the report that deals with the mesh. If there's something that's in the report that I don't know about  MR. ANDERSON: The only issue, Dave, is that he said that a lot of	4 5 6 7 8 9 10 11 12 13 14 15 16 17	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.  MR. THOMAS: They're not. No.  MR. ANDERSON: They're grouped together.  MR. THOMAS: Okay.  MR. ANDERSON: There we go. If you find the dark ones, it makes it easier.  MR. THOMAS: The first one that
5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did.  Have we covered it all?  MR. ANDERSON: Objection. With "whether you've covered it all."  MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think I've covered every sentence in the report that deals with the mesh. If there's something that's in the report that I don't know about  MR. ANDERSON: The only issue, Dave, is that he said that a lot of the slides that you can't put those	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.  MR. THOMAS: They're not. No.  MR. ANDERSON: They're grouped together.  MR. THOMAS: Okay.  MR. ANDERSON: There we go. If you find the dark ones, it makes it easier.  MR. THOMAS: The first one that I have here appears to be and
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did.  Have we covered it all?  MR. ANDERSON: Objection. With "whether you've covered it all."  MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think I've covered every sentence in the report that deals with the mesh. If there's something that's in the report that I don't know about  MR. ANDERSON: The only issue, Dave, is that he said that a lot of the slides that you can't put those types of fields into a one-dimensional	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.  MR. THOMAS: They're not. No.  MR. ANDERSON: They're grouped together.  MR. THOMAS: Okay.  MR. ANDERSON: There we go. If you find the dark ones, it makes it easier.  MR. THOMAS: The first one that I have here appears to be and they're not numbered so I can't give
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did.  Have we covered it all?  MR. ANDERSON: Objection. With "whether you've covered it all."  MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think I've covered every sentence in the report that deals with the mesh. If there's something that's in the report that I don't know about  MR. ANDERSON: The only issue, Dave, is that he said that a lot of the slides that you can't put those types of fields into a one-dimensional report, and I told you that I would provide you mine and you were going to send me your guy's. So whether or not	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.  MR. THOMAS: They're not. No.  MR. ANDERSON: They're grouped together.  MR. THOMAS: Okay.  MR. ANDERSON: There we go. If you find the dark ones, it makes it easier.  MR. THOMAS: The first one that I have here appears to be and they're not numbered so I can't give you a page number, but in Exhibit 11, the first one that I have appears to match the one on page 71.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did.  Have we covered it all?  MR. ANDERSON: Objection. With "whether you've covered it all."  MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think I've covered every sentence in the report that deals with the mesh. If there's something that's in the report that I don't know about  MR. ANDERSON: The only issue, Dave, is that he said that a lot of the slides that you can't put those types of fields into a one-dimensional report, and I told you that I would provide you mine and you were going to	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	make that a little easier.  MR. THOMAS: Thank you.  Are they in order?  MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.  MR. THOMAS: They're not. No.  MR. ANDERSON: They're grouped together.  MR. THOMAS: Okay.  MR. ANDERSON: There we go. If you find the dark ones, it makes it easier.  MR. THOMAS: The first one that I have here appears to be and they're not numbered so I can't give you a page number, but in Exhibit 11, the first one that I have appears to

69 (Pages 610 to 613)

	Page 614		Page 616
1	see if they're all of them are	1	MR. THOMAS: Those are all of
2	listed. We just have to count them.	2	the questions I have.
3	There's 13 images in the back that I	3	CROSS EXAMINATION
4	count of the report and you're in the	4	QUESTIONS BY MR. ANDERSON:
5	middle of them right now.	5	Q. Dr. Klinge, you were asked a
6	MR. THOMAS: Let's go to the	6	few questions a few minutes ago by counsel
7	last one.	7	regarding whether or not you had a residency
8	MR. ANDERSON: Show me which	8	or a fellowship in pathology.
9	slide.	9	Do you remember those
10	QUESTIONS BY MR. THOMAS:	10	questions?
11	Q. The last slide that I have in	11	A. Yes.
12	front of me, I'm sorry, it's not numbered,	12	Q. Dr. Klinge, approximately when
13	but it's BAL 13-23, which is the patient	13	did you begin reviewing pathology slides of
14	identifier. On the right, it has a scale of	14	explanted meshes?
15	100 microns, and in the middle of the slide,	15	A. We I started to have a look
16	it shows what appears to be a measurement of	16	through the microscope to these explanted
17	43.15 microns.	17	meshes in 1994.
18	Is that a that's the one on	18	Q. And was that as part of the
19	page 73?	19	work with the IZKF-BIOMAT cross-functional
20	A. Uh-huh.	20	team at Aachen University?
21	Q. Is that right?	21	A. It was in relation to this
22	A. Seems to. Yeah, I will agree.	22	project with the IZKF in collaboration with
23	MR. THOMAS: So you counted 13?	23	Professor Klosterhalfen at that time.
24	MR. ANDERSON: I think that's	24	Q. Is it fair to say that
	Page 615		Page 617
1	right.	1	Dr. Klosterhalfen trained you as a
2	MR. THOMAS: And there are 13	2	pathologist to review the histopathological
3	in the report.	3	slides of foreign body reaction to implanted
4	(Klinge Exhibit 25 marked for	4	meshes?
5	identification.)	5	MR. THOMAS: Object to the form
6	QUESTIONS BY MR. THOMAS:	6	of the question.
7	Q. Let me mark as Deposition	7	THE WITNESS: Yes.
8	Exhibit Number 25 the chart that we've been	8	QUESTIONS BY MR. ANDERSON:
9	consulting, correct?	9	Q. You said "yes"?
10	A. Yes.	10	A. Yes.
11	Q. And that's where you recorded	11	Q. Since that time in 1994 when
12	your findings from your review of the slides	12	you first began looking at slides from either
13	that we've been discussing, correct?	13	animals or human tissue of explanted meshes,
14	A. Yes, these are my results.	14	approximately how many times have you
15	Q. And it also includes the	15	reviewed such slides and analyzed them? How
16	information that Mr. Anderson provided about	16	many slides?
17	the chain of custody and the source of	17	A. How many slides? It's
18	documents that you received, fair?	18	difficult to estimate, but I've I estimate
19	A. Yes.	19	it's more than 25,000.
20	Q. Dr. Klinge, did you ever tell	20	Q. And as part of your review of
21	Ethicon that they should not sell the	21	over 25,000 slides of the histopathology of
	•		
22	Prolene® mesh used for the treatment of	22	explanted meshes, have you also published on
	Prolene® mesh used for the treatment of stress urinary incontinence?  A. No.	22 23 24	explanted meshes, have you also published on some of those reviews?  MR. THOMAS: Object to the form

70 (Pages 614 to 617)

	Page 618		Page 620
1	of the question.	1	for this case; is that correct?
2	QUESTIONS BY MR. ANDERSON:	2	A. Yes, that's correct, I never
3	Q. In the peer-reviewed	3	talked to him.
4	literature?	4	Q. Yesterday counsel was asking
5	A. Yes. Yes.	5	you some questions about this time period
6	Q. And have there been times where	6	from 1994 to 2000 when you were in this
7	you have published in the peer-reviewed	7	cross-functional team with the IZKF-BIOMAT in
8	literature where you were the only	8	Aachen with the group Ethicon Norderstedt.
9	pathologist that was reviewing the slides for	9	Do you recall that part of your
10	the work that was contained in the study?	10	testimony?
11	A. Yes.	11	A. Yes.
12	MR. THOMAS: Object to the form	12	Q. He asked you whether that time
13	of the question.	13	period dealt with the treatment of stress
14	QUESTIONS BY MR. ANDERSON:	14	urinary incontinence.
15	Q. You said "yes"?	15	So my question is this:
16	A. Yes.	16	Dr. Klinge, do you consider that your work
17	Q. Okay. And have you presented	17	that you did in the '90s in developing VYPRO
18	at Congresses and conferences to your	18	and in working with this BIOMAT team, the
19	colleagues and others with regard to your	19	publications that you've done over the last
20	analysis of histopathological review of	20	20 years, the conferences you've spoken at
21	slides from explanted tissue in either humans	21	and all of the work that you've done in this
22	or animals?	22	field of biomaterial research and the tissue
23	MR. THOMAS: Object to the form	23	response to surgical meshes as well as your
24	of the question.	24	work as a hernia surgeon relates equally to
	Page 619		Page 621
1	THE WITNESS: Yes. And it is a	1	hernia surgery mesh and the body's reaction
2	common procedure that a scientist made	2	to it, pelvic organ prolapse mesh and the
3	his own personal analysis of the	3	body's reaction to it and sling mesh and the
4	tissues and made the analysis and the	4	body's reaction to it?
5	presentation of these data by himself.	5	MR. THOMAS: Object to the form
6	QUESTIONS BY MR. ANDERSON:	6	of the question.
7	Q. A little while ago counsel was	7	THE WITNESS: In regard to the
8	asking you some questions about your choice	8	biological response to these meshes,
9	of using the S100 staining with regard to	9	to these hernia meshes, there are a
10	your review of these 22 explants.	10	lot of similarities that allows us to
11	Do you recall that part?	11	make conclusions for both of this.
12	A. Yes.	12	There are, of course, severe
13	Q. He also asked you some	13	differences or significant differences
14	questions to which you responded that this	14	in regard to functional analysis or
15	was something that you and Bernd	15	biomechanics, but the tissue reaction
16	Klosterhalfen had discussed many years ago	16	to a polymer is a lot of similarities.
17 18	about the choice of \$100.	17  18	QUESTIONS BY MR. ANDERSON:
19	Do you remember that part of	19	Q. Is one of the similarities that
20	your question? A. Yes.	20	all of this work that we've been discussing
21		21	for the last two days and the things that I listed in my former question to you help
22	Q. When you were answering these questions, you were talking strike that.	22	scientists like yourself try to predict the
23	You never talked to	23	tissue response to particular surgical
24	Dr. Klosterhalfen about whether to use S100	24	meshes?
4	DI. MOSICINATION ADOUT WHETHER TO USE \$100		mesnes:

71 (Pages 618 to 621)

	Page 622		Page 624
1	MR. THOMAS: Object to the form	1	concept, therefore, it includes what
2	of the question.	2	we have collaborated for the VYPRO,
	THE WITNESS: Yes, in fact, it		but the specific details of the
4			textile construction, there we haven't
5	these years that allow us to make this	4 5	been involved.
6	analysis, to define requirements for	6	QUESTIONS BY MR. ANDERSON:
7	textiles in this field and it is	7	Q. Okay. Yesterday counsel asked
8	usually very appreciated when we	8	you some questions about Exhibit 9, which
9	present our experiences of these	9	were the meeting minutes from the Suvretta
10	15 years to urogynecologists.	10	meeting in 2003 in St. Moritz.
11	QUESTIONS BY MR. ANDERSON:	11	Do you remember that?
12	Q. Thank you, Doctor.	12	A. Yes.
13	Yesterday counsel asked you	13	Q. And he asked you some questions
14	some questions as well regarding whether or	14	about the part of your presentation where you
15	not anyone in Aachen had a direct role in the	15	were discussing whether a scar plate or a
16	development of ULTRAPRO <sup>TM</sup> .	16	scar net might begin to that would appear
17	Do you recall those questions?	17	to be between 600 and 800 microns.
18	A. Yes.	18	Do you remember that part of
19	Q. Whether or not anyone had a	19	your testimony yesterday?
20	direct role in the research and development	20	A. Yes.
21	of ULTRAPRO <sup>TM</sup> , do you consider the work that	21	Q. I want to show you what we've
22	you and your team in conjunction with Ethicon	22	marked as Klinge Deposition Number 26 to your
23	did on VYPRO to be the foundational	23	deposition.
24	principles upon which ULTRAPRO™ was designed?	24	(Klinge Exhibit 26 marked for
	Page 623		Page 625
1	A. I think it was quite clear that	1	identification.)
2	ULTRAPRO™ was the successor of the VYPRO, and	2	QUESTIONS BY MR. ANDERSON:
3	it just replaced an oligofilament mesh	3	Q. Do you recognize this
4	materials by monofilament and what we tried	4	publication?
5	with the IZKF funding where we tried to do	5	A. Yes.
6	and realized with the PVDF that was done by	6	Q. And this is a publication in
7	Ethicon with polypropylene and Monocryl. And	7	2002 in the Journal of Surgical Research?
8	as a consequence, I guess that, therefore, I	8	A. Yes.
9	got royalties for the ULTRAPROTM, not only for	9	Q. And are you one of the authors
10	the VYPRO because of this close relationship.	10	along with those from the BIOMAT the
11	Q. So is it fair to say that you	11	IZKF-BIOMAT group?
12	were receiving royalties for ULTRAPRO™ sales	12	A. Yes, I was the author.
13	at the same time that you were telling	13	Q. And if you turn to the very
14	Ethicon that you believed and that the Aachen	14	last page under the "Acknowledgements"
15	group believed that PVDF was a superior	15	section as well as at the bottom of the page,
16	material to polypropylene?	16	does this indicate who provided funding?
17 18	MR. THOMAS: Object to the form	17	A. Yes.
19	of the question.	18	Q. And which company provided
20	THE WITNESS: There is an everlapping time period there	19 20	funding to this research?  A Most supported by Ethicon and
21	overlapping time period there.	20	A. Most supported by Ethicon and by the IZKF-BIOMAT.
22	So, again, just to make it clear, ULTRAPRO <sup>TM</sup> took over the	22	Q. Because this was the time
23	principles of the VYPRO, the large	23	this is the time that you're working closely
24	pore concept, the material reduced	24	with them on developing VYPRO?
	pore concept, the material reduced		with them on developing viliku:

72 (Pages 622 to 625)

Page 626 Page 628 No, this was after this time 1 presentation in 2000, 2001 showing the 1 2 2 where we developed the VYPRO, but it was the distribution of the pores based on the Marlex 3 3 time where we worked close together and had mesh and there we indicated that there may be 4 several ongoing projects together. 4 a -- that in these specimen that we measured 5 And if we turn to page 213 of 5 at that time there was a limit in between 6 this article from 2002, if we look to the 6 600, 800 microns. 7 7 left-hand column, down where the words begin In the other article, we want "As a result," what does that say? 8 8 to express that a -- wanted to say or to be 9 Does it say, "As a result, the 9 on a -- in a range that -- where you can 10 large pore sized greater than 2-millimeter 10 expect that you get pores without this mesh is integrated in a loose network of 11 bridging, there we find this is 1 millimeter 11 12 perifilimentary granulomas and plenty of fat 12 and in between, I guess, there has been the 13 tissue in between. Whereas the monofilament 13 experiment that later on has been published by Conze with IPOM where we again measured 14 mesh with its smaller pores almost 14 15 exclusively is imbedded into granulomas and 15 all of these distances. scar tissue which bridges the whole pore 16 16 So, yeah, we learned that it diameter of less than 1 millimeter"? 17 17 depends from the polymer that is affected by 18 Did I read that correctly? 18 the animal model there, but, however, we 19 19 wanted to give a range or to give a hint A. Yes. 20 Q. Does that language that you've 20 where the border lays and, therefore, we said 21 seen appear in Ethicon documents? 21 1 millimeter. 2.2 A. Yes. 2.2 If you look to the documents 23 MR. THOMAS: Object to the form 23 later on, in the presence of tension, 24 of the question. 24 Klosterhalfen advised 3 millimeters in some Page 627 Page 629 1 1 THE WITNESS: Yes, I've seen it meetings there, and so I've no disagreement 2 in many documents, and I'm sure I have 2 to this. So you see that there was a 3 repeated many of these phrases 3 evolution of these advises and you have to be 4 carefully looking to the specific conditions 4 vesterday and today. Because it's 5 5 in what condition this was expressed there. still our belief. 6 6 And during that time period in **QUESTIONS BY MR. ANDERSON:** 7 7 the late '90s and early 2000s, were most of Q. And given that -- strike that. So this journal article that 8 the heavy-weight, small pore meshes somewhere 8 9 was published in -- based upon studies that 9 in this 600 to 1,000-micron pore size? were funded, at least in part by Ethicon, was 10 10 MR. THOMAS: Object to the form 11 in 2002, and your presentation in St. Moritz 11 of the question. 12 was in 2003. 12 **OUESTIONS BY MR. ANDERSON:** 13 13 So my question is you've listed In a linear measurement? O. 14 a limit of 1,000 microns in the 2002 article 14 Yeah. We didn't realize that 15 with regard to a limit where fibrotic 15 the Prolene® is around this 1 millimeter in 16 bridging may be seen, whereas in the panel 16 this. And maybe that there will be an discussion in Suvretta in 2003, you listed 17 17 upcoming question whether this millimeter is 18 600 to 800 microns. 18 enough or it's not enough. If we have known at that time that this may be a problem, we 19 Can you please explain that? 19 20 A. At that time, we had -- we made 20 would have thought a little bit more 21 several attempts to make measure the pore and 21 precisely to find maybe another border, to 22 22 the bridging and we started at that time with find another border there. 23 23 the Marlex mesh and before I saw somewhere in Whether the limit is at 24 the documents that there is a PowerPoint 24 950 microns and 1,050 microns, is it safe to

73 (Pages 626 to 629)

	Page 630		Page 632
1	say that in all of the explants of Prolene®	1	to now with regard to the fibrotic bridging
2	old construction 6-mil mesh, whether it was	2	you've seen with Prolene®?
3	in the explants that you looked at from	3	MR. THOMAS: Object to the form
4	animal studies back during your time working	4	of the question.
5	with Ethicon or in any of the explants that	5	THE WITNESS: Again, it is
6	had been done both in the 1,000 hernia	6	clear that it is normal for a high
7	explants as well as the greater than 400	7	risk with a mesh for high risk for
8	explants that have been looked at from the	8	fibrosis. For a high-risk mesh, this
9	pelvic floor, have you consistently had an	9	is a normal reaction.
10	observation with regard to the way Prolene®	10	QUESTIONS BY MR. ANDERSON:
11	old construction 6-mil mesh that's used in	11	Q. And do you believe that the
12	the TVT® slings reacts in the tissue in terms	12	Prolene old construction 6-mil mesh used in
13	of its pore size?	13	TVT® is a high-risk mesh with regard to
14	MR. THOMAS: Object to the form	14	heavy-weight, small pore mesh that leads to
15	of the question.	15	fibrotic bridging and complications in
16	QUESTIONS BY MR. ANDERSON:	16	patients?
17	Q. Have you noticed any sort of	17	MR. THOMAS: Object to the form
18	pattern or consistency there?	18	of the question.
19	MR. THOMAS: Same objection.	19	THE WITNESS: It's a high risk
20	THE WITNESS: In all of these	20	in regard to the extent of
21	sample that we had a look to it,	21	inflammation, scarring, shrinkage,
22	Prolene® behaves as a heavy-weight,	22	dimension or the amount of material.
23	small pore mesh regardless whatever	23	QUESTIONS BY MR. ANDERSON:
24	figures are printed out. The	24	Q. And do you hold that opinion to
	Page 631		Page 633
1	morphology of the tissue examination,	1	a reasonable degree of medical and scientific
2	with the extent of the geometry of the	2	certainty?
3	scar formation makes it clear that the	3	A. Absolutely. I'm convinced of
4	old Prolene® is a behaves like a	4	it and there's huge evidence for this.
5	small pore heavy-weight, small pore	5	(Klinge Exhibit 27 marked for
6	mesh.	6	identification.)
7	QUESTIONS BY MR. ANDERSON:	_	
_	QUESTIONS BY MIKE THE BERSON.	7	QUESTIONS BY MR. ANDERSON:
8	Q. And a few minutes ago when	8	QUESTIONS BY MR. ANDERSON: Q. I show you what I've marked as
9		l .	Q. I show you what I've marked as Klinge Exhibit Number 27.
	Q. And a few minutes ago when	8	Q. I show you what I've marked as
9 10 11	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT®	8 9	Q. I show you what I've marked as Klinge Exhibit Number 27.
9 10 11 12	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT® meshes, he asked you is this a normal	8 9 10 11 12	Q. I show you what I've marked as Klinge Exhibit Number 27. Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia
9 10 11 12 13	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue	8 9 10 11 12 13	Q. I show you what I've marked as Klinge Exhibit Number 27. Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005?
9 10 11 12 13 14	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue response.	8 9 10 11 12 13 14	Q. I show you what I've marked as Klinge Exhibit Number 27. Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005? Have you seen this before?
9 10 11 12 13 14 15	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue response.  Do you remember those types of	8 9 10 11 12 13 14	Q. I show you what I've marked as Klinge Exhibit Number 27. Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005? Have you seen this before? A. Yes, I've seen it before.
9 10 11 12 13 14 15	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue response.  Do you remember those types of questions?	8 9 10 11 12 13 14 15	Q. I show you what I've marked as Klinge Exhibit Number 27. Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005? Have you seen this before? A. Yes, I've seen it before. Q. And do you know these authors,
9 10 11 12 13 14 15 16	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue response.  Do you remember those types of questions?  A. Yes.	8 9 10 11 12 13 14 15 16	Q. I show you what I've marked as Klinge Exhibit Number 27. Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005? Have you seen this before? A. Yes, I've seen it before. Q. And do you know these authors, William Cobb, Kent Kercher and Todd Heniford?
9 10 11 12 13 14 15 16 17	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue response.  Do you remember those types of questions?  A. Yes.  Q. And you said your testimony	8 9 10 11 12 13 14 15 16 17	Q. I show you what I've marked as Klinge Exhibit Number 27. Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005? Have you seen this before? A. Yes, I've seen it before. Q. And do you know these authors, William Cobb, Kent Kercher and Todd Heniford? A. Yes, I know them.
9 10 11 12 13 14 15 16 17 18	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue response.  Do you remember those types of questions?  A. Yes.  Q. And you said your testimony was normal or what we usually see with regard	8 9 10 11 12 13 14 15 16 17 18	Q. I show you what I've marked as Klinge Exhibit Number 27. Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005? Have you seen this before? A. Yes, I've seen it before. Q. And do you know these authors, William Cobb, Kent Kercher and Todd Heniford? A. Yes, I know them. Q. And is Todd Heniford the hernia
9 10 11 12 13 14 15 16 17 18 19 20	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue response.  Do you remember those types of questions?  A. Yes.  Q. And you said your testimony was normal or what we usually see with regard to a heavy-weight, small pore mesh.	8 9 10 11 12 13 14 15 16 17 18 19 20	Q. I show you what I've marked as Klinge Exhibit Number 27. Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005? Have you seen this before? A. Yes, I've seen it before. Q. And do you know these authors, William Cobb, Kent Kercher and Todd Heniford? A. Yes, I know them. Q. And is Todd Heniford the hernia surgeon that you mentioned with reference to
9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue response.  Do you remember those types of questions?  A. Yes.  Q. And you said your testimony was normal or what we usually see with regard to a heavy-weight, small pore mesh.  Do you remember that part of	8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. I show you what I've marked as Klinge Exhibit Number 27. Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005? Have you seen this before? A. Yes, I've seen it before. Q. And do you know these authors, William Cobb, Kent Kercher and Todd Heniford? A. Yes, I know them. Q. And is Todd Heniford the hernia surgeon that you mentioned with reference to the Suvretta conference in 2003?
9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue response.  Do you remember those types of questions?  A. Yes. Q. And you said your testimony was normal or what we usually see with regard to a heavy-weight, small pore mesh.  Do you remember that part of your testimony?	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. I show you what I've marked as Klinge Exhibit Number 27. Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005? Have you seen this before? A. Yes, I've seen it before. Q. And do you know these authors, William Cobb, Kent Kercher and Todd Heniford? A. Yes, I know them. Q. And is Todd Heniford the hernia surgeon that you mentioned with reference to the Suvretta conference in 2003? A. Yeah, I met him there and at
9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue response.  Do you remember those types of questions?  A. Yes.  Q. And you said your testimony was normal or what we usually see with regard to a heavy-weight, small pore mesh.  Do you remember that part of	8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. I show you what I've marked as Klinge Exhibit Number 27. Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005? Have you seen this before? A. Yes, I've seen it before. Q. And do you know these authors, William Cobb, Kent Kercher and Todd Heniford? A. Yes, I know them. Q. And is Todd Heniford the hernia surgeon that you mentioned with reference to the Suvretta conference in 2003?

74 (Pages 630 to 633)

	Page 634		Page 636
1	reviewing materials that I've sent you, that	1	sentence in Dr. Heniford's article, it says,
2	Dr. Heniford is an expert for Ethicon in this	2	"In contrast, the small pore mesh was
3	litigation?	3	incorporated entirely in perifilimentary
4	A. Even more, he's an expert for	4	granulomas and scar tissue which bridged the
5	the argument of light-weight polypropylene.	5	whole pore diameter of less than 1
6	Of the use of light-weight meshes.	6	millimeter."
7	Q. If we turn to Dr. Heniford's	7	Did I read that correctly?
8	publication, on page 2, which on this	8	A. Yes.
9	publication is on page 64 at the top left of	9	Q. And we have the diagrams down
10	Exhibit 27, what is the weight listed for	10	below showing that, "A 4-millimeter pore size
11	Prolene®?	11	will not show the granulomas touching of a
12	A. Prolene® here, it's given	12	light-weight mesh, whereas a 0.8-millimeter
13	105-gram per square meters.	13	pore size does have the granulomas touching
14	Q. And it's lighter or heavier	14	of a heavy-weight mesh."
15	than Marlex?	15	Do you see that?
16	A. It is heavier.	16	A. Yes, I see that.
17	Q. And if we turn over to page 67	17	Q. So according to this article,
18	of this article by Dr. Heniford and his	18	would Dr. Heniford and his colleagues'
19	colleagues, do you see the section "Degree of	19	opinions be consistent with your own with
20	Shrinkage"?	20	regard to the percentage of shrinkage of
21	A. Yes, I see it.	21	meshes in vivo as well as the limit of around
22	Q. And reading under there, "One	22	1,000 microns to prevent fibrotic bridging?
23	concern with the long-term implantation of	23	MR. THOMAS: Object to the form
24	mesh is the amount of shrinkage or passive	24	of the question.
	Page 635		Page 637
1	compression the material undergoes. All	1	THE WITNESS: All of these
2	available meshes regardless of their	2	statements by published or
3	composition, experience a 20 to 50 percent	3	concluded in this manuscript confirms
4	reduction in their initial size."	4	my opinions in regard to shrinkage and
5	Did I read that correctly?	5	required pore size to prevent
6	A. Yes.	6	bridging.
7	Q. Was that the state of knowledge	7	QUESTIONS BY MR. ANDERSON:
8	as of 2005 based upon your understanding and	8	Q. And if we look to the left
9	your work that meshes could shrink from 20 to	9	under the paragraph that begins, "In a dog
10	50 percent?	10	model," does that paragraph indicate that
11	MR. THOMAS: Object to the form	11	polypropylene meshes shrink 30 to 50 percent
12	of the question.	12	of their original size within two to six
13	THE WITNESS: Yes, I agree.	13	months after implantation.
14	QUESTIONS BY MR. ANDERSON:	14	Do you see that?
15	Q. Is that part of what you were	15	A. Yes, I see it.
16	testifying to earlier when answering	16	Q. Is that consistent with the
17	Mr. Thomas's questions regarding amount of	17	opinions that you've stated to counsel here
18	shrinkage that you can expect from	18	today?
19	polypropylene meshes in the human body?	19	A. Yeah. It is it confirms
20	A. It's in accordance to what I	20	that the extent of shrinkage is higher in
21	said.	21	heavy-weight when using heavy-weight
22	Q. If you turn over to page 68, in	22	materials and can be reduced by using
	this Heniford article, if you look down to	23	material-reduced meshes.
23 24	the second the column on the right in the	24	Q. And these ideas of the amount

75 (Pages 634 to 637)

	Page 638		Page 640
1	of contraction that could be expected in vivo	1	seen this document before?
2	of polypropylene meshes, was this information	2	A. Yes, I've seen it.
3	that Ethicon was aware of as a result of your	3	Q. And if we turn over into the
4	work with them going back to the '90s?	4	document where it says "pore size" from this
5	MR. THOMAS: Object to the form	5	presentation in at Ethicon February 23,
6	of the question.	6	2007, does that page indicate on a slide by
7	THE WITNESS: Yes. And yeah.	7	Kirsten Spychaj, "Small porous meshes less
8	MR. THOMAS: Can we take a real	8	than 1 millimeter lead to fibrotic bridging
9	quick break?	9	and increase shrinkage"?
10	MR. ANDERSON: Yeah.	10	A. Yeah.
11	MR. THOMAS: Just ten seconds.	11	Q. "Large porous meshes allow for
12	(Off the record at 4:44 p.m.)	12	a better and faster tissue ingrowth and less
13	QUESTIONS BY MR. ANDERSON:	13	shrinkage and contraction"?
14	Q. I don't remember the exhibit	14	A. That is a correct summary.
15	that we had with Professor Klosterhalfen with	15	Q. And down below where it says,
16	this document the other day, but if we have	16	"less than 1 millimeter" in the three little
17	the minutes from 2007.	17	circles, these are drawings that you've seen
18	I'm going to show you what we	18	before?
19	marked the other day as Klosterhalfen	19	A. Yes, I've seen it.
20	Exhibit 11, which are the minutes from the	20	Q. And these little red dots,
21	meeting in Norderstedt in 2007.	21	would those indicate the peri-filamentous
22	You've seen this document	22	granulomas that you were referring to
23	before?	23	earlier?
24	A. Yes, I've seen it.	24	MR. THOMAS: Object to the form
2 1	Page 639	21	Page 641
1	Q. And at that meeting, if you	1	of the question.
2	turn to page 2, do you see a heading "Factors	2	THE WITNESS: Maybe it can be
3	Related to Mesh Shrinkage"?	3	interpreted in this way.
4	A. Yes.	4	QUESTIONS BY MR. ANDERSON:
5	Q. By a Ms. Spychaj?	5	Q. So this would be a depiction of
6	A. Yes.	6	the size of pores after implanted in the body
7	Q. S-p-y-c-h-a-j.	7	as a depiction of that, correct?
8	MR. THOMAS: Object to the form	8	MR. THOMAS: Object to the form
9	of the questions related to that	9	of the question.
10	document. Was he at that meeting?	10	THE WITNESS: That is correct.
11	Was he shown being in attendance?	11	It's quite similar to the images that
12	MR. ANDERSON: I don't know.	12	have been in the publication from
13	It doesn't show him being there.	13	Heniford.
14	MR. THOMAS: That's what I	14	QUESTIONS BY MR. ANDERSON:
15	thought. Just a continued objection	15	Q. And have you seen this image of
16	to his comments because he wasn't	16	pores less than 1 millimeter leading to
17	there.	17	fibrotic bridging that we see here on I'll
18	MR. ANDERSON: Sure. I don't	18	have to mark this as Plaintiff's Exhibit 28.
19	think he has to be present at meetings	19	(Klinge Exhibit 28 marked for
20	to be able to look at the PowerPoints	20	identification.)
21	that were there.	21	QUESTIONS BY MR. ANDERSON:
22	QUESTIONS BY MR. ANDERSON:	22	Q. Is this an image that you've
23	Q. And this PowerPoint entitled	23	seen many times throughout the Ethicon

76 (Pages 638 to 641)

two years in these litigations?  A. Yes, many times. Many times.  And I've never seen any document showing that this is not a fact.  Q. Have you seen in any of the peer-reviewed literature in the last 20 years anyone who has disputed the fact that you need greater than I millimeter pore size to prevent fibrotic bridging in the tissues?  MR. THOMAS: Object to the form of the question.  THE WITNESS: No. (Klinge Exhibit 29 marked for identification.)  MR. THOMAS: Object to the form of the question.  THE WITNESS: No. (I don't know. In the worldwide peer-reviewed last 20 years, have you seen this - share you seen this - have you seen th		Page 642		Page 644
2 And I've never seen any document showing that this is not a fact.  4 And I've never seen any document showing that this is not a fact.  5 Q. Have you seen in any of the peer-reviewed literature in the last 20 years anyone who has disputed the fact that you need greater than I millimeter pore size to prevent fibrotic bridging in the tissues?  10 MR. THOMAS: Object to the form of the question.  11 of the question.  12 THE WITNISS: No, I don't know.  13 No, any study, any discussion that claimed to have facts that are in contradiction to this finding, to this estimate, to this interpretation.  14 claimed to have facts that are in contradiction to this finding, to this estimate, to this interpretation.  15 QUESTIONS BY MR. ANDERSON:  16 estimate, to this interpretation.  17 QUESTIONS BY MR. ANDERSON:  18 Questinate, to this interpretation.  19 literature over the last 20 years, have you seen any scientist or surgeon who has published regarding looking at has published regarding studies either looking at an animal explanted mesh or human explanted mesh who have indicated that light-weight, large  Page 643  1 pore meshes versus heavy-weight, small pore meshes, that the heavy-weight, small pore meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that J just gave you?  10 THE WITNESS: Do less. Larger pore, lighter weight meshes do not? Has anyone in 20 years any researchers other than of the question.  10 THE WITNESS: Do less. Larger pore, lighter weight meshes do not? Has anyone in 20 years are futted those findings based upon the indications that J just gave you?  11 never saw or were confronted with some captanet meshes form both an indication that plate and the provided peer-reviewed worldwide publication in the last 20 years any researchers other than yourself and Dr. Klosterhalfen who have incideated that light-weight and provided as many	1	two years in these litigations?	1	of the question.
And I've never seen any document showing that this is not a fact.  Q. Have you seen in any of the peer-reviewed literature in the last 20 years anyone who has disputed the fact that you need greater than I millimeter pore size to prevent fibrotic bridging in the tissues? MR. THOMAS: Object to the form of the question. THE WITNESS: No, I don't know. No, any study, any discussion that claimed to have facts that are in contradiction to this finding, to this estimate, to this interpretation.  Q. In the worldwide peer-reviewed life literature over the last 20 years, have you seen any scientist or surgeon who has published regarding looking at has published regarding studies either looking at animal explanted mesh or human explanted mesh who have indicated that light-weight, large  pore meshes versus heavy-weight, small pore meshes, that the heavy-weight, small pore meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you?  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I never saw or were confronted with someone disputing this findings.  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I never saw or were confronted with someone disputing this findings.  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I never saw or were confronted with someone disputing this findings.  Q. Have you ever seen in the peer-reviewed worldwide publication in the last 20 years any researchers other than yourself and Dr. Klosterhalfen who have provided worldwide publication in the last 20 years any rescanchres other than yourself and Dr. Klosterhalfen who have provided worldwide publication in the list as the maximum pore size in millimeters?  A. The			2	*
this is not a fact.  Q. Have you seen in any of the peer-reviewed literature in the last 20 years anyone who has disputed the fact that you need greater than I millimeter pore size to prevent fibrotic bridging in the tissues? THE WTINESS: No, I don't know.  Q. Okay. An e-mail from Joerg Log vars, have you Log vars, have you Literature over the last 20 years, have you published regarding looking at − has published regarding studies either looking at animal explanted mesh or human explanted mesh who have indicated that light-weight, small pore meshes, that the heavy-weight, small pore meshes, that the heavy-weight, small pore meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you?  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger of the question.  Page 643  por meshes versus heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years forfuted those findings based upon the indications that I just gave you?  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger pore meshes versus heavy-weight, small pore meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years forfuted those findings based upon the indications that I just gave you?  QUESTIONS BY MR. ANDERSON:  A. Yes, I see it. Q. And is this Joerg Holste that  Yours With Ethicon to develop YYPRO?  A. That's true. (Klinge Exhibit 30  This is a Klinge = -sorry, this is a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical director, Ethicon, depar				
5 Q. Have you seen in any of the 6 peer-reviewed literature in the last 20 years 7 anyone who has disputed the fact that you 8 need greater than I millimeter pore size to 9 prevent fibrotic bridging in the tissues? 10 MR. THOMAS: Object to the form 11 of the question. 11 2 THE WITNESS: No, I don't know. 12 13 No, any study, any discussion that 13 claimed to have facts that are in 14 claimed to have facts that are in 15 contradiction to this finding, to this 16 estimate, to this interpretation. 16 Q. In the worldwide peer-reviewed 17 guestions By MR. ANDERSON: 18 Q. Man. THOMAS: Object to the form 19 literature over the last 20 years, have you 20 seen any scientist or surgeon who has 21 published regarding looking at −has 22 published regarding studies either looking at 23 animal explanted mesh or human explanted mesh 24 who have indicated that light-weight, large 25 meshes, that the heavy-weight, small pore 26 meshes, that the heavy-weight, small pore 27 meshes induce fibrotic bridging and scarring 28 and contraction, whereas larger pore, lighter 29 of the question. 10 THE WITNESS: No, I don't know. 20 In the worldwide publication in the 21 poor meshes versus heavy-weight, small pore 22 meshes, that the heavy-weight, small pore 23 meshes induce fibrotic bridging and scarring 24 and contraction, whereas larger pore, lighter 25 weight meshes do not? Has anyone in 20 years 26 refuted those findings based upon the 27 indications that I just gave you? 28 MR. THOMAS: Object to the form 29 of the question. 20 SENDING BY MR. ANDERSON: 21 published regarding looking at −has 22 published regarding looking at −has 23 published regarding looking at −has 24 who have indicated that light-weight, large 25 meshes, that the heavy-weight, small pore 26 meshes, that the heavy-weight, small pore 27 meshes induce fibrotic bridging and contraction, whereas larger pore, lighter 38 minute port has a proper of the form 39 of the question. 30 This is a Klinge Exhibit 29, have you seen this − have you seen this − have you seen this − ha				, ,
6 peer-reviewed literature in the last 20 years anyone who has disputed the fact that you need greater than I millimeter pore size to prevent fibrotic bridging in the tissues?  10 MR. THOMAS: Object to the form of the question.  11 No, any study, any discussion that claimed to have facts that are in claimed to				· · · · · · · · · · · · · · · · · · ·
amyone who has disputed the fact that you need greater than I millimeter pore size to prevent fibrotic bridging in the tissues?  MR. THOMAS: Object to the form of the question.  THE WITNESS: No, I don't know.  No, any study, any discussion that 1 claimed to have facts that are in contradiction to this finding, to this estimate, to this interpretation.  QUESTIONS BY MR. ANDERSON: 17  QUESTIONS BY MR. ANDERSON: 17  QUESTIONS BY MR. ANDERSON: 17  In pore meshes versus heavy-weight, small pore meshes, that the heavy-weight, small pore meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you?  MR. THOMAS: Object to the form 10 to this finding. 10 this pore do less fibrotic reaction, but I never saw or were confronted with someome disputing this findings. 10 the peer-reviewed worldwide publication in the last 20 years any researchers other than 10 to the page four pages back, which ends in Bates number 5782, under Polenc®, what does he list as the maximum pore size in millimeters? A. The pore size of less than 1			6	•
8 prevent fibrotic bridging in the tissues?  10 MR. THOMAS: Object to the form of the question.  11 of the question.  12 THE WITNESS: No, I don't know.  13 No, any study, any discussion that claimed to have facts that are in claimed to have fac				
9 prevent fibrotic bridging in the tissues? 10 MR. THOMAS: Object to the form 11 of the question. 12 THE WITNESS: No, I don't know. 13 No, any study, any discussion that 14 claimed to have facts that are in 15 contradiction to this finding, to this 16 estimate, to this interpretation. 17 QUESTIONS BY MR. ANDERSON: 18 Q. In the worldwide peer-reviewed 19 literature over the last 20 years, have you 20 seen any scientist or surgeon who has 21 published regarding studies either looking at animal explanted mesh or human explanted mesh 24 who have indicated that light-weight, large 25 meshes, that the heavy-weight, small pore meshes, that the heavy-weight, small pore meshes, induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you? 26 MR. THOMAS: Object to the form of the question. 27 MR. THOMAS: Object to the form of the question. 28 MR. THOMAS: Object to the form of the question. 29 MR. THOMAS: Object to the form of the question. 20 MR. THOMAS: Object to the form of the question. 21 QUESTIONS BY MR. ANDERSON: 22 MR. THOMAS: Object to the form of the question. 23 M. No. 24 No. 25 Q. And in the first line, 26 Janual the first line, 27 Jonathan, the border for scar plate formation in small pore standard weight meshes was set around 1,000 microns." 28 Joyou see that? 29 Joyou see that? 20 Joyou see that? 21 Joyou have worked with since the '90's going back all the way back to your IZKF-BIOMAT work with Ethicion to devolp VYPRO? 22 Joyou have worked with since the '90's going back all the way back to your IZKF-BIOMAT work with Ethicion to devolp VYPRO? 24 A. That's true. 25 (Klinge Exhibit 30 marked for identification.) 26 Q. Showing what we will mark as Klinge Exhibit 30. 27 This is a Klinge — sorry, this is a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical director, Ethicon, department of medical director, Ethicon, department of medical	8		8	Č
10			9	
11 of the question. 12 THE WITNESS: No, I don't know. 13 No, any study, any discussion that 14 claimed to have facts that are in 15 contradiction to this finding, to this 16 estimate, to this interpretation. 17 QUESTIONS BY MR. ANDERSON: 18 Q. In the worldwide peer-reviewed 19 literature over the last 20 years, have you 20 seen any scientist or surgeon who has 21 published regarding looking at has 22 published regarding studies either looking at 23 animal explanted mesh or human explanted mesh 24 who have indicated that light-weight, small pore 25 meshes, that the heavy-weight, small pore 26 meshes, that the heavy-weight, small pore 27 meshes induce fibrotic bridging and scarring 28 and contraction, whereas larger pore, lighter 29 weight meshes do not? Has anyone in 20 years 29 for the question. 20 Cokay. An e-mail from Joerg 21 A. Yes, I see it. 20 And in the first line, 21 Jonathan, the border for scar plate forestens around 1,000 microns." 20 Do you see that? 21 A. Yes, I see it. 22 A. Yes, I see it. 23 A. Yes, I see it. 24 Voun have worked with since the '90s going back all the way back to your IZKF-BIOMAT 25 work with Ethicon to develop VYPRO? 26 A. That's true. 27 (Klinge Exhibit 30 marked for identification.) 28 MR. THOMAS: Object to the form of the question. 29 of the question. 20 Showing what we will mark as 21 published regarding studies either looking at animal explanted mesh or human				
12 THE WITNESS: No, I don't know. 13 No, any study, any discussion that 14 claimed to have facts that are in 15 contradiction to this finding, to this 16 estimate, to this interpretation. 17 QUESTIONS BY MR. ANDERSON: 18 Q. In the worldwide peer-reviewed 19 literature over the last 20 years, have you 20 see any scientist or surgeon who has 21 published regarding looking at has 22 published regarding studies either looking at 23 animal explanted mesh or human explanted mesh 24 who have indicated that light-weight, large 25 weight meshes versus heavy-weight, small pore 26 meshes, that the heavy-weight, small pore 27 meshes induce fibrotic bridging and scarring 28 and contraction, whereas larger pore, lighter 29 weight meshes do not? Has anyone in 20 years 20 refuted those findings based upon the 21 indications that 1 just gave you? 28 MR. THOMAS: Object to the form 29 of the question. 20 Have you ever seen in the 21 pores do less fibrotic reaction, but 1 21 never saw or were confronted with 21 someone disputing this findings. 21 QUESTIONS BY MR. ANDERSON: 22 published regarding looking at has 23 A. Yes, I see it. Q. And in the first line, 19 Jonathan, the border for scar plate formation in small pore standard weight meshes was set around 1,000 microns." 20 you see that? 21 A. Yes, I see it. Q. And is this Joerg Holste that 22 you have worked with since the '90s going back all the way back to your IZKF-BIOMAT work with Ethicon to develop VYPRO? 22 A. That's true. 23 (Klinge Exhibit 30 marked for identification.) 24 (Klinge Exhibit 30 marked for identification). 25 (Senary and contraction, but 1 never saw or were confronted with someone disputing this findings. 26 (Klinge Exhibit 30 marked for identification). 27 (QUESTIONS BY MR. THOMAS: Q. Showing what we will mark as 28 (Klinge Exhibit 30 marked for identification). 38 (Lingation). 39 (MR. THOMAS: Object to the form of the question. 30 (MR. THOMAS: Object to the form of the question. 31 (MR. THOMAS: Object to the form of the question. 32 (MR. THOMAS: Objec		· · · · · · · · · · · · · · · · · · ·		•
No, any study, any discussion that claimed to have facts that are in contradiction to this finding, to this estimate, to this interpretation.  QUESTIONS BY MR. ANDERSON: Q. In the worldwide peer-reviewed literature over the last 20 years, have you seen any scientist or surgeon who has published regarding looking at has published regarding studies either looking at animal explanted mesh or human explanted mesh who have indicated that light-weight, large  Page 643  pore meshes versus heavy-weight, small pore meshes, that the heavy-weight, small pore meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you?  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I never saw or were confronted with someone disputing this findings.  QUESTIONS BY MR. ANDERSON:  THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I someone disputing this findings.  QUESTIONS BY MR. ANDERSON:  Q. Have you ever seen in the peer-reviewed worldwide publication in the last 20 years any researchers other than yourself and Dr. Klosterhalfen who have reviewed as many explanted meshes from both animals and human beings for hernia, POP and SUI and reported on those in the worldwide literature, any other scientists other than  13				
claimed to have facts that are in contradiction to this finding, to this contradiction to this finding, to this interpretation.  QUESTIONS BY MR. ANDERSON:  In the worldwide peer-reviewed  literature over the last 20 years, have you seen any scientist or surgeon who has published regarding looking at has published regarding studies either looking at animal explanted mesh or human explanted mesh who have indicated that light-weight, large  Page 643  Page 644  Page 644  Page 645  pore meshes versus heavy-weight, small pore meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you?  MR. THOMAS: Object to the form of the question.  MR. THOMAS: Object to the form of the question.  MR. THOMAS: Object to the form of the question.  MR. THOMAS: Object to the form of the question.  MR. THOMAS: Object to the form of the question.  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I never saw or were confronted with someone disputing this findings.  QUESTIONS BY MR. ANDERSON:  QUESTIONS BY MR. ANDERS				· ·
contradiction to this finding, to this estimate, to this interpretation.  QUESTIONS BY MR. ANDERSON:  Recomption of the question.  Contradiction to this findings.  Contradiction to this findings, to this estimate, to this interpretation.  QUESTIONS BY MR. ANDERSON:  Recomption of the question.  Contradiction to this findings.  Contradiction to this findings, to this estimate, to this interpretation.  Contradiction to the worldwide publication in the useful and reported on those in the worldwide labeling and sarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you?  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I never saw or were confronted with someone disputing this findings.  QUESTIONS BY MR. THOMAS:  Contradiction the worldwide publication in the last 20 years any researchers other than yourself and Dr. Klosterhalfen who have reviewed as many explanted meshes from both animals and human beings for hernia, POP and SUI and reported on those in the worldwide labeliance in millimeters?  London the first line, Tondina the first line, Tondina the brother in small pore standard weight meshes was set around 1,000 microns.  A. Yes, I see it.  Q. And is this Joerg Holste that  work with Ethicon to develop VYPRO?  A. That's true.  (Klinge Exhibit 30.  This is a Klinge - sorry, this is a clinical expert r				
16 estimate, to this interpretation. 17 QUESTIONS BY MR. ANDERSON: 18 Q. In the worldwide peer-reviewed 19 literature over the last 20 years, have you 20 seen any scientist or surgeon who has 21 published regarding looking at has 22 published regarding studies either looking at 23 animal explanted mesh or human explanted mesh 24 who have indicated that light-weight, large 25 pore meshes versus heavy-weight, small pore 26 meshes, that the heavy-weight, small pore 27 meshes induce fibrotic bridging and scarring 28 and contraction, whereas larger pore, lighter 29 weight meshes do not? Has anyone in 20 years 20 for fequestion. 21 pore does fibrotic reaction, but I 22 never saw or were confronted with 23 someone disputing this findings. 24 QUESTIONS BY MR. ANDERSON: 25 Larger 26 pore does fibrotic reaction, but I 27 never saw or were confronted with 28 guestions that Just gave yor? 39 of the question. 40 A. Yes, I see it. 41 Q. And in the first line, 42 I'onathan, the border for scar plate 42 formation in small pore standard weight 42 meshes was set around 1,000 microns." 43 A. Yes, I see it. 44 Q. And is this Joerg Holste that 45 Q. And is this Joerg Holste that 46 You have worked with since the '90s going back all the way back to your IZKF-BIOMAT 47 work with Ethicon to develop VYPRO? 48 A. That's true. 49 You have worked with since the '90s going back all the way back to your IZKF-BIOMAT 40 work with Ethicon to develop VYPRO? 41 A. That's true. 42 Q. Showing what we will mark as 43 Will have you ker seen in the peer-reviewed worldwide publication in the last 20 years any researchers other than 40 yourself and Dr. Klosterhalfen who have reviewed as many explanted meshes from both animals and human beings for hernia, POP and 20 If you turn over to the page four pages back, which ends in Bates number 5782, under Prolen@, what does he list as the maximum pore size in millimeters? 41 A. Yes, I see it. 42 Q. And is this Joerg Holste that 42 Q. Showing the weight meshes don't have will mark as 43 Will have worked wit				
17 QUESTIONS BY MR. ÁNDERSON: 18 Q. In the worldwide peer-reviewed 19 literature over the last 20 years, have you 20 seen any scientist or surgeon who has 21 published regarding looking at has 22 published regarding studies either looking at 23 animal explanted mesh or human explanted mesh 24 who have indicated that light-weight, large  Page 643  1 pore meshes versus heavy-weight, small pore 2 meshes, that the heavy-weight, small pore 3 meshes induce fibrotic bridging and scarring 4 and contraction, whereas larger pore, lighter 5 weight meshes do not? Has anyone in 20 years 6 refuted those findings based upon the 1 indications that I just gave you? 8 MR. THOMAS: Object to the form 9 of the question. 10 THE WITNESS: Do less. Larger 11 pores do less fibrotic reaction, but I 12 never saw or were confronted with 13 someone disputing this findings. 14 QUESTIONS BY MR. ANDERSON: 15 Q. Have you ever seen in the 16 peer-reviewed worldwide publication in the 18 last 20 years any researchers other than 19 reviewed as many explanted meshes from both 20 animals and human beings for hernia, POP and 21 literature, any other scientists other than 22 literature, any other scientists other than 24 A. Yes, I see it.  Q. And is this Joer hose weight meshes was set around 1,000 microns." 22 po you see that? 24 A. Yes, I see it. Q. And is this Joerg Holste that 25 you have worked with since the '90s going back all the way back to your IZKF-BIOMAT 3 work with Ethicon to develop VYPRO? 4 A. That's true. 5 (Klinge Exhibit 30 marked for identification.) 6 (Klinge Exhibit 30 marked for identification.) 7 QUESTIONS BY MR. ANDERSON: 10 THE WITNESS: Do less. Larger 11 pove saw or were confronted with 12 never saw or were confronted with 13 someone disputing this findings. 14 QUESTIONS BY MR. ANDERSON: 15 Q. Have you ever seen in the 16 peer-reviewed worldwide publication in the 17 last 20 years any researchers other than 18 Q. If you turn over to the page four pages back, which ends in Bates number 5782, under Prolene®, what does he lis		•		
18 Q. In the worldwide peer-reviewed 19 literature over the last 20 years, have you 20 seen any scientist or surgeon who has 21 published regarding looking at has 22 published regarding studies either looking at 23 animal explanted mesh or human explanted mesh 24 who have indicated that light-weight, large  Page 643  1 pore meshes versus heavy-weight, small pore 2 meshes, that the heavy-weight, small pore 3 meshes induce fibrotic bridging and scarring 4 and contraction, whereas larger pore, lighter 5 weight meshes do not? Has anyone in 20 years 6 refuted those findings based upon the 7 indications that I just gave you? 8 MR. THOMAS: Object to the form 9 of the question. 10 THE WITNESS: Do less. Larger 11 pores do less fibrotic reaction, but I 12 never saw or were confronted with 13 someone disputing this findings. 14 Q. And is this Joerg Holste that  Page 645  Page 645  Page 645  Vou have worked with since the '90s going back all the way back to your IZKF-BIOMAT work with Ethicon to develop VYPRO?  4 A. That's true. (Klinge Exhibit 30 marked for identification.) QUESTIONS BY MR. THOMAS: Q. Showing what we will mark as Klinge Exhibit 30.  This is a Klinge sorry, this is a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical affairs. Q. Have you ever seen in the peer-reviewed worldwide publication in the last 20 years any researchers other than previewed as many explanted meshes from both animals and human beings for hermia, POP and SUI and reported on those in the worldwide 22 literature, any other scientists other than  18 Q. And is this for omation in small pore standard weight meshes was set around 1,000 microns."  Do you see that?  A. Yes, I see it. Q. Mat give you?  Klinge Exhibit 30 marked for identification.)  This is a Klinge sorry, this is a clinical expert report from Piet Hinoul, medical affairs.  Do you see that?  A. That's true. (Klinge Exhibit 30 marked for identification.)  This is a Klinge sorry, this is a clinical expert report from Piet Hinoul, m				•
19 literature over the last 20 years, have you seen any scientist or surgeon who has 21 published regarding looking at has 22 published regarding studies either looking at 22 animal explanted mesh or human explanted mesh 24 who have indicated that light-weight, large 27 por meshes versus heavy-weight, small pore 28 meshes, that the heavy-weight, small pore 29 meshes, that the heavy-weight, small pore 20 meshes induce fibrotic bridging and scarring 34 and contraction, whereas larger pore, lighter 36 weight meshes do not? Has anyone in 20 years 37 refuted those findings based upon the 39 of the question. 39 of the question. 30 THE WITNESS: Do less. Larger 30 pores do less fibrotic reaction, but 1 never saw or were confronted with 31 someone disputing this findings. 31 QUESTIONS BY MR. ANDERSON: 31 QUESTIONS BY MR. ANDERSON: 31 QUESTIONS BY MR. ANDERSON: 31 poer weight meshes from both 31 animals and human beings for hernia, POP and 32 Using at a nimal explanted mesh of the question. 30 marked for identification. 30 marked for identification. 31 identification. 32 USESTIONS BY MR. THOMAS: 32 USESTIONS BY MR. ANDERSON: 31 medical affairs. 32 USESTIONS BY MR. ANDERSON: 31 poer section, but 1 prever saw or were confronted with 32 poer section, but 1 prevention of the peer-reviewed worldwide publication in the 34 pourself and Dr. Klosterhalfen who have 35 reviewed as many explanted meshes from both 36 animals and human beings for hernia, POP and 35 Ust and reported on those in the worldwide 32 literature, any other scientists other than 32 voin see that? 32 pour see that? 34 vor with Ethicon to develop VYPRO? 4A. That's true. (Klinge Exhibit 30 marked for identification.) 35 marked for identification.) 36 marked for identification.) 37 pour later work with Ethicon to develop VYPRO? 4D. This is a Clinical expert report from Piet Hinoul, 38 medical affairs. 39 pour see that? 4D. A. Yes, 1 see it. 4D. A. Yes,			l .	·
seen any scientist or surgeon who has published regarding looking at has published regarding studies either looking at animal explanted mesh or human beings for hermia, POP and StII and reported on those in the worldwide lateration.				•
published regarding looking at has published regarding studies either looking at animal explanted mesh or human beings for hemia, POP and or human beings		• • • • • • • • • • • • • • • • • • • •		
published regarding studies either looking at animal explanted mesh or human explanted mesh who have indicated that light-weight, large  Page 643  pore meshes versus heavy-weight, small pore meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you?  MR. THOMAS: Object to the form soft the question.  THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I never saw or were confronted with since the '90s going work with Ethicon to develop VYPRO?  A. That's true.  (Klinge Exhibit 30 marked for identification.)  QUESTIONS BY MR. THOMAS:  Q. Showing what we will mark as Klinge Exhibit 30.  This is a klinge sorry, this is a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical affairs.  QUESTIONS BY MR. ANDERSON: 14 Do you see that?  A. Yes, I see it.  Q. And is this Joerg Holste that  Page 645  A. Yes, I see it.  Q. And is this Joerg Holste that  Page 645  A. Yes, I see it.  Q. And is this Joerg Holste that  Page 645  A. That's true.  (Klinge Exhibit 30 marked for identification.)  QUESTIONS BY MR. THOMAS:  Q. Showing what we will mark as Klinge Exhibit 30.  This is a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical affairs.  QUESTIONS BY MR. ANDERSON: 14 Do you see that?  A. Yes, I see it.  Q. Hove you ever seen in the 15 A. Yes, I see it.  Q. It's dated September 25, 2012?  A. Yes, I see it.  Q. If you turn over to the page four pages back, which ends in Bates number 5782, under Prolene®, what does he list as the maximum pore size in millimeters?  A. The pore size of less than 1				
animal explanted mesh or human explanted mesh who have indicated that light-weight, large  Page 643  pore meshes versus heavy-weight, small pore meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years feetuted those findings based upon the indications that I just gave you?  MR. THOMAS: Object to the form of the question.  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger pore, lighter than pore saw or were confronted with never saw or were confronted with since the '90s going back all the way back to your IZKF-BIOMAT work with Ethicon to develop VYPRO?  A. That's true.  (Klinge Exhibit 30 marked for identification.)  QUESTIONS BY MR. THOMAS:  No Showing what we will mark as thinge sorry, this is a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical affairs.  Q. Have you ever seen in the pory you see that?  A. Yes, I see it.  Q. Have you ever seen in the pory you see that?  A. Yes, I see it.  Q. If's dated September 25, 2012?  A. Yes.  Q. If you turn over to the page four pages back, which ends in Bates number 5782, under Prolene®, what does he list as the maximum pore size in millimeters?  A. Yes the port of the				
24   who have indicated that light-weight, large   24   Q. And is this Joerg Holste that				•
Page 643  pore meshes versus heavy-weight, small pore meshes, that the heavy-weight, small pore meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you?  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I pores do less fibrotic reaction, but I pores awo or were confronted with someone disputing this findings.  QUESTIONS BY MR. ANDERSON:  QUESTIONS BY MR. ANDERSON:  Do you see that?  Q. Have you ever seen in the peer-reviewed worldwide publication in the last 20 years any researchers other than yourself and Dr. Klosterhalfen who have reviewed as many explanted meshes from both animals and human beings for hernia, POP and SUI and reported on those in the worldwide literature, any other scientists other than literature, and the way back to your IZKF-BIOMAT work with Ethicon to develop VYPRO?  A. That's true.  (Klinge Exhibit 30 marked for identification.)  That's true.  (Klinge Exhibit 30 marked for identification.)  That's true.  (Klinge E				·
meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you?  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I mever saw or were confronted with someone disputing this findings.  QUESTIONS BY MR. ANDERSON: QUESTIONS BY MR. THOMAS: QUESTIONS BY MR. THOM				
meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you?  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I mever saw or were confronted with someone disputing this findings.  QUESTIONS BY MR. ANDERSON: QUESTIONS BY MR. THOMAS: QUESTIONS BY MR. THOM	1	nore meshes versus heavy-weight small nore	1	you have worked with since the '90s going
meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years frefuted those findings based upon the midications that I just gave you?  MR. THOMAS: Object to the form of the question.  THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I never saw or were confronted with someone disputing this findings.  QUESTIONS BY MR. THOMAS:  Klinge Exhibit 30.  This is a Klinge sorry, this is a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical affairs.  QUESTIONS BY MR. ANDERSON:  MR. THOMAS:  Unique Exhibit 30.  This is a Klinge sorry, this is a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical affairs.  Do you see that?  A. Yes, I see it.  Unique Exhibit 30 marked for identification.)  RUESTIONS BY MR. THOMAS:  Klinge Exhibit 30.  This is a Klinge sorry, this is a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical affairs.  A. Yes, I see it.  Unique Exhibit 30 marked for identification.)  RUESTIONS BY MR. THOMAS:  RUESTIONS BY MR. THOMAS:  Now K with Ethicon to develop VYPRO?  A. That's true.  (Klinge Exhibit 30 marked for identification.)  RUESTIONS BY MR. THOMAS:  RU		· · · · · · · · · · · · · · · · · · ·		
4 and contraction, whereas larger pore, lighter 5 weight meshes do not? Has anyone in 20 years 6 refuted those findings based upon the 7 indications that I just gave you? 8 MR. THOMAS: Object to the form 9 of the question. 10 THE WITNESS: Do less. Larger 11 pores do less fibrotic reaction, but I 12 never saw or were confronted with 13 someone disputing this findings. 14 QUESTIONS BY MR. ANDERSON: 15 Q. Have you ever seen in the 16 peer-reviewed worldwide publication in the 17 last 20 years any researchers other than 18 yourself and Dr. Klosterhalfen who have 19 reviewed as many explanted meshes from both 20 animals and human beings for hernia, POP and 21 SUI and reported on those in the worldwide 22 literature, any other scientists other than 21 Climate A. That's true. 22 (Klinge Exhibit 30 marked for identification.) 24 A. This is a Klinge sorry, this is a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical affairs. 24 Do you see that? 25 A. Yes, I see it. 26 Q. It's dated September 25, 2012? 27 A. The pore size of less than 1				
5 weight meshes do not? Has anyone in 20 years 6 refuted those findings based upon the 7 indications that I just gave you? 8 MR. THOMAS: Object to the form 9 of the question. 10 THE WITNESS: Do less. Larger 11 pores do less fibrotic reaction, but I 12 never saw or were confronted with 13 someone disputing this findings. 14 QUESTIONS BY MR. ANDERSON: 15 Q. Have you ever seen in the 16 peer-reviewed worldwide publication in the 17 last 20 years any researchers other than 18 yourself and Dr. Klosterhalfen who have 19 reviewed as many explanted meshes from both 20 animals and human beings for hernia, POP and 21 SUI and reported on those in the worldwide 22 literature, any other scientists other than 21 crefuted those findings based upon the 22 dictarding by each of the identification.) 22 (Klinge Exhibit 30 marked for identification.) 2 QUESTIONS BY MR. THOMAS: 24 QUESTIONS BY MR. THOMAS: 25 (Klinge Exhibit 30 marked for identification.) 26 QUESTIONS BY MR. THOMAS: 26 Naning Exhibit 30 marked for identification.) 27 QUESTIONS BY MR. THOMAS: 28 Q. Showing what we will mark as 29 Klinge Exhibit 30. 20 This is a Clinical expert report from Piet Hinoul, 21 medical director, Ethicon, department of 21 medical director, Ethicon, department of 21 medical affairs. 22 Do you see that? 23 Do you see that? 24 Do you see that? 25 Q. It's dated September 25, 2012? 26 A. Yes. 27 Q. If you turn over to the page 28 four pages back, which ends in Bates 29 number 5782, under Prolene®, what does he 20 list as the maximum pore size in millimeters? 29 A. The pore size of less than 1				
forefuted those findings based upon the indications that I just gave you?  8 MR. THOMAS: Object to the form 9 of the question.  9 of the question.  10 THE WITNESS: Do less. Larger 10 This is a Klinge sorry, this 11 pores do less fibrotic reaction, but I 11 is a clinical expert report from Piet Hinoul, 12 mever saw or were confronted with 12 medical director, Ethicon, department of 13 someone disputing this findings.  14 QUESTIONS BY MR. ANDERSON: 14 Do you see that?  15 Q. Have you ever seen in the 15 A. Yes, I see it.  16 peer-reviewed worldwide publication in the 16 Q. It's dated September 25, 2012?  17 last 20 years any researchers other than 17 A. Yes.  18 yourself and Dr. Klosterhalfen who have 18 Q. If you turn over to the page 19 reviewed as many explanted meshes from both 20 animals and human beings for hernia, POP and 21 SUI and reported on those in the worldwide 22 literature, any other scientists other than 22 A. The pore size of less than 1			l .	
7 indications that I just gave you? 8 MR. THOMAS: Object to the form 9 of the question. 10 THE WITNESS: Do less. Larger 11 pores do less fibrotic reaction, but I 12 never saw or were confronted with 13 someone disputing this findings. 14 QUESTIONS BY MR. ANDERSON: 15 Q. Have you ever seen in the 16 peer-reviewed worldwide publication in the 17 last 20 years any researchers other than 18 yourself and Dr. Klosterhalfen who have 19 reviewed as many explanted meshes from both 20 animals and human beings for hernia, POP and 21 SUI and reported on those in the worldwide 22 literature, any other scientists other than  17 QUESTIONS BY MR. THOMAS:  8 Q. Showing what we will mark as  Klinge Exhibit 30.  10 This is a Klinge sorry, this 11 is a clinical expert report from Piet Hinoul, 12 medical director, Ethicon, department of 13 medical affairs. 14 Do you see that? 15 A. Yes, I see it. 16 Q. It's dated September 25, 2012? 17 A. Yes. 18 Q. If you turn over to the page 19 four pages back, which ends in Bates 19 number 5782, under Prolene®, what does he 20 literature, any other scientists other than 21 SUI and reported on those in the worldwide 22 literature, any other scientists other than		• •	l .	
8 MR. THOMAS: Object to the form 9 of the question. 10 THE WITNESS: Do less. Larger 11 pores do less fibrotic reaction, but I 12 never saw or were confronted with 13 someone disputing this findings. 14 QUESTIONS BY MR. ANDERSON: 15 Q. Have you ever seen in the 16 peer-reviewed worldwide publication in the 17 last 20 years any researchers other than 18 yourself and Dr. Klosterhalfen who have 19 reviewed as many explanted meshes from both 20 animals and human beings for hernia, POP and 21 SUI and reported on those in the worldwide 22 literature, any other scientists other than  10 This is a Klinge sorry, this 11 is a clinical expert report from Piet Hinoul, 12 medical director, Ethicon, department of 13 medical affairs. 14 Do you see that? 15 A. Yes, I see it. 16 Q. It's dated September 25, 2012? 17 A. Yes. 18 Q. If you turn over to the page 19 four pages back, which ends in Bates 19 number 5782, under Prolene®, what does he 21 list as the maximum pore size in millimeters? 22 A. The pore size of less than 1			l .	
9		υ <b>υ</b>	l .	
THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I never saw or were confronted with someone disputing this findings.  QUESTIONS BY MR. ANDERSON: CHave you ever seen in the less to peer-reviewed worldwide publication in the last 20 years any researchers other than yourself and Dr. Klosterhalfen who have reviewed as many explanted meshes from both animals and human beings for hernia, POP and SUI and reported on those in the worldwide literature, any other scientists other than literature any other scientists other than literature and the ported on those in the worldwide literature, any other scientists other than literature and the ported on those in the worldwide literature and the ported on those in the worldwide literature and the ported on those in the worldwide literature and the ported on the ported on the ported on those in the worldwide literature and the ported on the ported		· · · · · · · · · · · · · · · · · · ·		
pores do less fibrotic reaction, but I never saw or were confronted with someone disputing this findings.  QUESTIONS BY MR. ANDERSON:  Question of the peer-reviewed worldwide publication in the last 20 years any researchers other than yourself and Dr. Klosterhalfen who have reviewed as many explanted meshes from both animals and human beings for hernia, POP and SUI and reported on those in the worldwide literature, any other scientists other than list a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical affairs.  13 medical affairs.  4. Yes, I see it.  Q. If you turn over to the page four pages back, which ends in Bates number 5782, under Prolene®, what does he list as the maximum pore		•		· ·
never saw or were confronted with someone disputing this findings.  QUESTIONS BY MR. ANDERSON:  Q. Have you ever seen in the last 20 years any researchers other than yourself and Dr. Klosterhalfen who have reviewed as many explanted meshes from both animals and human beings for hernia, POP and SUI and reported on those in the worldwide literature, any other scientists other than  nedical director, Ethicon, department of medical affairs.  La Ves, I see it.  Q. It's dated September 25, 2012?  A. Yes.  Q. If you turn over to the page number 5782, under Prolene®, what does he list as the maximum pore size in millimeters? A. The pore size of less than 1				
someone disputing this findings.  14 QUESTIONS BY MR. ANDERSON:  15 Q. Have you ever seen in the  16 peer-reviewed worldwide publication in the  17 last 20 years any researchers other than  18 yourself and Dr. Klosterhalfen who have  19 reviewed as many explanted meshes from both  20 animals and human beings for hernia, POP and  21 SUI and reported on those in the worldwide  22 literature, any other scientists other than  13 medical affairs.  14 Do you see that?  A. Yes, I see it.  16 Q. It's dated September 25, 2012?  17 A. Yes.  18 Q. If you turn over to the page  19 four pages back, which ends in Bates  20 number 5782, under Prolene®, what does he  21 list as the maximum pore size in millimeters?  22 A. The pore size of less than 1		<b>.</b>		* *
14 QUESTIONS BY MR. ANDERSON: 15 Q. Have you ever seen in the 16 peer-reviewed worldwide publication in the 17 last 20 years any researchers other than 18 yourself and Dr. Klosterhalfen who have 19 reviewed as many explanted meshes from both 20 animals and human beings for hernia, POP and 21 SUI and reported on those in the worldwide 22 literature, any other scientists other than 24 Do you see that? 25 A. Yes, I see it. 26 Q. It's dated September 25, 2012? 27 A. Yes. 28 Q. If you turn over to the page 29 four pages back, which ends in Bates 20 number 5782, under Prolene®, what does he 21 list as the maximum pore size in millimeters? 22 A. The pore size of less than 1				
Q. Have you ever seen in the peer-reviewed worldwide publication in the last 20 years any researchers other than yourself and Dr. Klosterhalfen who have reviewed as many explanted meshes from both animals and human beings for hernia, POP and SUI and reported on those in the worldwide literature, any other scientists other than  A. Yes, I see it.  Q. It's dated September 25, 2012?  A. Yes.  Q. If you turn over to the page four pages back, which ends in Bates number 5782, under Prolene®, what does he list as the maximum pore size in millimeters? A. The pore size of less than 1		1 0		
peer-reviewed worldwide publication in the last 20 years any researchers other than yourself and Dr. Klosterhalfen who have reviewed as many explanted meshes from both animals and human beings for hernia, POP and SUI and reported on those in the worldwide literature, any other scientists other than  16 Q. It's dated September 25, 2012?  A. Yes.  Q. If you turn over to the page four pages back, which ends in Bates number 5782, under Prolene®, what does he list as the maximum pore size in millimeters?  A. The pore size of less than 1		-		
17 last 20 years any researchers other than 18 yourself and Dr. Klosterhalfen who have 19 reviewed as many explanted meshes from both 20 animals and human beings for hernia, POP and 21 SUI and reported on those in the worldwide 22 literature, any other scientists other than  17 A. Yes. 18 Q. If you turn over to the page 19 four pages back, which ends in Bates 20 number 5782, under Prolene®, what does he 21 list as the maximum pore size in millimeters? 22 A. The pore size of less than 1		- ·		·
yourself and Dr. Klosterhalfen who have reviewed as many explanted meshes from both animals and human beings for hernia, POP and SUI and reported on those in the worldwide literature, any other scientists other than  Q. If you turn over to the page four pages back, which ends in Bates number 5782, under Prolene®, what does he list as the maximum pore size in millimeters? A. The pore size of less than 1		*		· · · · · · · · · · · · · · · · · · ·
reviewed as many explanted meshes from both animals and human beings for hernia, POP and SUI and reported on those in the worldwide literature, any other scientists other than  19 four pages back, which ends in Bates number 5782, under Prolene®, what does he list as the maximum pore size in millimeters? A. The pore size of less than 1				
20 animals and human beings for hernia, POP and 21 SUI and reported on those in the worldwide 22 literature, any other scientists other than 20 number 5782, under Prolene®, what does he 21 list as the maximum pore size in millimeters? 22 A. The pore size of less than 1				
21 SUI and reported on those in the worldwide 22 literature, any other scientists other than 21 list as the maximum pore size in millimeters? 22 A. The pore size of less than 1		* *		
22 literature, any other scientists other than 22 A. The pore size of less than 1				
1 1				
23 the two of you? 23 millimeter.	23			
24 MR. THOMAS: Object to the form 24 Q. Thank you.				

77 (Pages 642 to 645)

	Page 646		Page 648
1	Showing you what we will mark	1	Q. Other than being listed in
2	as Klinge Exhibit 31 wait a minute.	2	this I am sorry, let's go to the cover
3	Actually you strike that.	3	page.
4	Showing you what was previously	4	It has, "Demand the most proven
5	marked by counsel as Klinge Exhibit 21.	5	technology when selecting a midurethral
6	There was this International Urogynecology	6	sling. Make data and safety your choice"
7	Journal from Moalli and some of her	7	with the surgeon on the front.
8	colleagues entitled "Tensile Properties of	8	Do you see that?
9	Five Commonly Used Midurethral Slings	9	A. Yes, I see it.
10	Relative to the TVT®" from May 2008.	10	Q. And in this document where they
11	Do you remember counsel showing	11	list 1,379 microns
12	you this?	12	A. Yes.
13	A. Yes, I remember.	13	Q based upon your review of
14	Q. And he showed you on the top of	14	the depositions and the testing and the
15	what is page 57 of this article, he showed	15	porosity and pore size evaluations by
16	you the pore size of Gynecare being listed as	16	numerous Ethicon employees, have you ever
17	1379.	17	seen any indication in any of those that
18	Do you see that?	18	there was a measurement of a pore size of
19	A. Yes, I see it.	19	Prolene® of 1,379 microns for the mesh used
20	Q. And at the top of that under	20	in TVT® anywhere in your review?
21	Table 1, it says, "Textile Properties	21	MR. THOMAS: Object to the form
22	Provided by the Manufacturers."	22	of the question.
23	Do you see that?	23	QUESTIONS BY MR. ANDERSON:
24	A. Yes, I see it.	24	Q. Other than on this promotional
	Page 647		Page 649
1	Q. Did you see there strike	1	document by Ethicon, based upon your review
2	that.	2	of the depositions of Dan Burkley and all of
3	There was some questions by	3	the other documents that you've seen, have
4	counsel about their measurements of the pore	4	you ever seen them come up with a number of
5	size in this article.	5	1,379?
6	Do you see anywhere in this	6	A. No, I didn't see it.
7	article where these authors measured these	7	Q. In fact, according to their
8	pore sizes?	8	medical affairs director, Piet Hinoul, in
9	A. No. As it is indicated there,	9	this 2012 expert report, which was Klinge
10	they took it from the manufacturer.	10	Exhibit 30, he says it's less than 1
11	(Klinge Exhibit 31 marked for	11	millimeter, correct?
12	identification.)	12	A. Yes.
13	QUESTIONS BY MR. ANDERSON:	13	MR. THOMAS: Object to the form
14	Q. Showing you what we will mark	14	of the question.
15	as Klinge Exhibit 31, under "Proprietary	15	QUESTIONS BY MR. ANDERSON:
16	Mesh," do you see here where they list there	16	Q. Going back to this Moalli
17	under "Proprietary Mesh," it says, "Largest	17	article turning to this page where it says
18	pore size"?	18	Figure 4, is this uniaxial testing that's
19	Do you see that?	19	being shown?
20	A. Yes, I see it.	20	A. Yes, it's uniaxial testing.
21	Q. And do you see 1379	21	It's quite similar to what we did with
22	1,379 microns listed here by the	22	Professor Mühl's machine.
$\sim$	manutacturar'/	23	Q. And these are the photos of A,
23 24	manufacturer? A. Yes, I see it.	24	B and C that you have as images in your

78 (Pages 646 to 649)

	Page 650		Page 652
1	report, correct?	1	Do you remember that part of
2	A. Yes.	2	your testimony?
3	Q. Okay. Doctor, I want to ask	3	A. Yes. Yes.
4	you one more thing about this Prolift+M®	4	Q. Okay. Do you consider the Mühl
5	document.	5	testing to be instructive to your opinions as
6	Here it shows a weight of what	6	to whether or not the Prolene® old
7	would be 76 grams per centimeter squared.	7	construction 6-mil mesh used in all of the
8	Do you see that?	8	TVT® devices has pores that are any pores
9	A. Yes, I see it.	9	that are 1 millimeter in diameter?
10	Q. So this would be a lighter	10	MR. THOMAS: Object to the form
11	Prolene® mesh than actually the old	11	of the question.
12	construction 6-mil mesh, correct?	12	THE WITNESS: There are some
13	A. Per the other yes.	13	pores around 1 millimeter.
14	Q. So would you expect the pore	14	QUESTIONS BY MR. ANDERSON:
15	size of the heavier weight Prolene® mesh to	15	Q. And would a Prolene® mesh that
16	be just as small, if not smaller, than the	16	has pores of pore area right around 1
17	Prolene® 76 grams per meter squared mesh?	17	millimeter be as safe as a pore size of
18	MR. THOMAS: Object to the form	18	ULTRAPRO <sup>TM</sup> or VYPRO with pores that are in the
19	of the question.	19	3 to 5 millimeter range in diameter?
20	THE WITNESS: It is difficult	20	MR. THOMAS: Object to the form
21	to for me to find this relation	21	of the question.
22	between weight and pore size.	22	THE WITNESS: No. It is very
23	QUESTIONS BY MR. ANDERSON:	23	clear that large pore meshes with 3, 4
24	Q. And when you were looking at	24	millimeters has very, very low risk,
	Page 651		Page 653
1	the pore size of Prolene® with	1	and it is clear that small pores mesh
2	Dr. Klosterhalfen back in the late '90s and	2	has higher risk. And biologically,
3	early 2000s, was it your best estimate as of	3	this is true for Prolene® because it
4	that time that the old construction 6-mil	4	bridges all the time. If you look to
5	Prolene® fibers used in all of the TVT®	5	the textile property the textile
6	devices had a pore size of 1,000 microns or	6	porosity, you see that the pores are
7	less?	7	around 1 millimeter. But if you look
8	MR. THOMAS: Object to the form	8	to the effective porosity, it is quite
9	of the question.	9	low. And, therefore, this is
10	THE WITNESS: It is when we	10	consistent.
11	made this linear measurements in one	11	(Klinge Exhibit 32 marked for
12	dimension, we got figures around 1	12	identification.)
13	millimeter. When we made analysis by	13	QUESTIONS BY MR. ANDERSON:
14	defining the area, we got figures	14	Q. Showing you what we will mark
			1/1: T 1:1:4:00 Id 1 4:1 4 I
15	around 1 millimeter. So it is	15	as Klinge Exhibit 32. It's a document that I
16	Prolene® has pores in this area.	16	have previously provided to you.
16 17	Prolene® has pores in this area. QUESTIONS BY MR. ANDERSON:	16 17	have previously provided to you.  Do you recall that, Dr. Klinge?
16 17 18	Prolene® has pores in this area.  QUESTIONS BY MR. ANDERSON:  Q. Over time I think over time	16 17 18	have previously provided to you.  Do you recall that, Dr. Klinge?  A. Yes.
16 17 18 19	Prolene® has pores in this area.  QUESTIONS BY MR. ANDERSON:  Q. Over time I think over time  I think you were telling counsel that rather	16 17 18 19	have previously provided to you.  Do you recall that, Dr. Klinge?  A. Yes.  Q. And if you look at the front
16 17 18 19 20	Prolene® has pores in this area.  QUESTIONS BY MR. ANDERSON:  Q. Over time I think over time  I think you were telling counsel that rather than using a linear dimension that the pore	16 17 18 19 20	have previously provided to you.  Do you recall that, Dr. Klinge?  A. Yes. Q. And if you look at the front page of this PowerPoint, are these the same
16 17 18 19 20 21	Prolene® has pores in this area.  QUESTIONS BY MR. ANDERSON:  Q. Over time I think over time I think you were telling counsel that rather than using a linear dimension that the pore diameter dimensions and the distribution of	16 17 18 19 20 21	have previously provided to you.  Do you recall that, Dr. Klinge?  A. Yes.  Q. And if you look at the front page of this PowerPoint, are these the same authors that we looked at in this Moalli,
16 17 18 19 20 21 22	Prolene® has pores in this area.  QUESTIONS BY MR. ANDERSON:  Q. Over time I think over time  I think you were telling counsel that rather than using a linear dimension that the pore diameter dimensions and the distribution of the pore area of 1 millimeter in diameter	16 17 18 19 20 21 22	have previously provided to you.  Do you recall that, Dr. Klinge?  A. Yes.  Q. And if you look at the front page of this PowerPoint, are these the same authors that we looked at in this Moalli, Abramowitch, Feola article that counsel
16 17 18 19 20 21	Prolene® has pores in this area.  QUESTIONS BY MR. ANDERSON:  Q. Over time I think over time I think you were telling counsel that rather than using a linear dimension that the pore diameter dimensions and the distribution of	16 17 18 19 20 21	have previously provided to you.  Do you recall that, Dr. Klinge?  A. Yes.  Q. And if you look at the front page of this PowerPoint, are these the same authors that we looked at in this Moalli,

79 (Pages 650 to 653)

	Page 654		Page 656
1	Q. And if you turn to the third	1	company in Aachen, FEG Textiltechnik, and the
2	page of this document, first of all, is the	2	inventors are U. Klinge and B. Klosterhalfen,
3	date, May 24, 2013?	3	RWTH Aachen, and two peoples from FEG."
4	A. Yes.	4	Do you see that?
5	Q. And if you look down into the	5	A. Yes, I see it.
6	middle slide on that page under "Material	6	Q. And then, "FEG has some
7	Parameters, Textile and Structural Properties	7	products for hernia repair on the market and
8	of Implant Materials," what does the sixth	8	also for pelvic floor surgery."
9	point say?	9	Did I read that correctly?
10	A. The sixth point means that	10	A. That is correct.
11	Q. What does it say, number 6?	11	Q. "In Germany, these products are
12	A. Effective porosity.	12	distributed through Dahlhausen, a big dealer
13	Q. And under "Biomechanics," does	13	for medical device."
14	it list the Mühl article that you did with	14	Do you see that?
15	Professor Mühl in 2008?	15	A. That is correct.
16	A. Yes.	16	Q. And then it talks about, "The
17	Q. From your reading of the Feola,	17	technology is based on a special material,
18	Abramowitch and Moalli article, was this your	18	PVDF."
19	understanding that this is a group out of	19	Do you see that?
20	Pittsburgh, Pennsylvania?	20	A. Yes.
21	A. Yes.	21	Q. And it says that, "Our
22	(Klinge Exhibit 33 marked for	22	material, Ethicon's material, Pronova is
23	identification.)	23	comparable to PVDF."
24	identification.)	24	Do you see that?
21	Page 655	21	Page 657
			5
1 1	OUESTIONS BY MR ANDERSON:	1	A Yes I see it
1 2	QUESTIONS BY MR. ANDERSON:  One last document I'm going	1 2	A. Yes, I see it. O. Is it your understanding that
2	Q. One last document. I'm going	2	Q. Is it your understanding that
2 3	Q. One last document. I'm going to show you Klinge Exhibit 33.	2 3	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that
2 3 4	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that	2 3 4	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?
2 3 4 5	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.	2 3 4 5	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago? MR. THOMAS: Object to the form
2 3 4 5 6	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph	2 3 4	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago? MR. THOMAS: Object to the form of the question.
2 3 4 5 6 7	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?	2 3 4 5 6 7	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago? MR. THOMAS: Object to the form of the question. THE WITNESS: Yes.
2 3 4 5 6 7 8	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.	2 3 4 5 6 7 8	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago? MR. THOMAS: Object to the form of the question. THE WITNESS: Yes. QUESTIONS BY MR. ANDERSON:
2 3 4 5 6 7 8 9	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had	2 3 4 5 6 7 8	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago? MR. THOMAS: Object to the form of the question. THE WITNESS: Yes. QUESTIONS BY MR. ANDERSON: Q. And you've seen that patent,
2 3 4 5 6 7 8 9	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked	2 3 4 5 6 7 8 9	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago? MR. THOMAS: Object to the form of the question. THE WITNESS: Yes. QUESTIONS BY MR. ANDERSON: Q. And you've seen that patent, correct?
2 3 4 5 6 7 8 9 10	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon	2 3 4 5 6 7 8 9 10	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago? MR. THOMAS: Object to the form of the question. THE WITNESS: Yes. QUESTIONS BY MR. ANDERSON: Q. And you've seen that patent, correct? A. Yes, I've seen it.
2 3 4 5 6 7 8 9 10 11 12	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?	2 3 4 5 6 7 8 9 10 11 12	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?     MR. THOMAS: Object to the form     of the question.     THE WITNESS: Yes. QUESTIONS BY MR. ANDERSON:     Q. And you've seen that patent, correct?     A. Yes, I've seen it.     Q. To your knowledge, has Ethicon
2 3 4 5 6 7 8 9 10 11 12 13	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?  A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago? MR. THOMAS: Object to the form of the question. THE WITNESS: Yes. QUESTIONS BY MR. ANDERSON: Q. And you've seen that patent, correct? A. Yes, I've seen it. Q. To your knowledge, has Ethicon ever acted upon that patent and tried to
2 3 4 5 6 7 8 9 10 11 12 13 14	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?  A. Yes.  Q. And even going back to your	2 3 4 5 6 7 8 9 10 11 12 13 14	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago? MR. THOMAS: Object to the form of the question. THE WITNESS: Yes. QUESTIONS BY MR. ANDERSON: Q. And you've seen that patent, correct? A. Yes, I've seen it. Q. To your knowledge, has Ethicon ever acted upon that patent and tried to produce a surgical mesh with PVDF in it for
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?  A. Yes.  Q. And even going back to your work with Ethicon from the late '90s in the	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?  MR. THOMAS: Object to the form of the question.  THE WITNESS: Yes.  QUESTIONS BY MR. ANDERSON: Q. And you've seen that patent, correct?  A. Yes, I've seen it. Q. To your knowledge, has Ethicon ever acted upon that patent and tried to produce a surgical mesh with PVDF in it for the pelvic floor or for hernia?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?  A. Yes.  Q. And even going back to your work with Ethicon from the late '90s in the development of VYPRO?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?     MR. THOMAS: Object to the form     of the question.         THE WITNESS: Yes. QUESTIONS BY MR. ANDERSON:     Q. And you've seen that patent, correct?     A. Yes, I've seen it.     Q. To your knowledge, has Ethicon ever acted upon that patent and tried to produce a surgical mesh with PVDF in it for the pelvic floor or for hernia?     A. I didn't ever get any positive
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?  A. Yes.  Q. And even going back to your work with Ethicon from the late '90s in the development of VYPRO?  A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?     MR. THOMAS: Object to the form     of the question.         THE WITNESS: Yes. QUESTIONS BY MR. ANDERSON:     Q. And you've seen that patent, correct?     A. Yes, I've seen it.     Q. To your knowledge, has Ethicon ever acted upon that patent and tried to produce a surgical mesh with PVDF in it for the pelvic floor or for hernia?     A. I didn't ever get any positive information for this.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?  A. Yes.  Q. And even going back to your work with Ethicon from the late '90s in the development of VYPRO?  A. Yes.  Q. And this is a letter from	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?         MR. THOMAS: Object to the form         of the question.             THE WITNESS: Yes.  QUESTIONS BY MR. ANDERSON:         Q. And you've seen that patent, correct?         A. Yes, I've seen it.         Q. To your knowledge, has Ethicon ever acted upon that patent and tried to produce a surgical mesh with PVDF in it for the pelvic floor or for hernia?         A. I didn't ever get any positive information for this.         Q. And then if we look at the next
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?  A. Yes.  Q. And even going back to your work with Ethicon from the late '90s in the development of VYPRO?  A. Yes.  Q. And this is a letter from Christoph Walther to Quentin.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?  MR. THOMAS: Object to the form of the question.  THE WITNESS: Yes.  QUESTIONS BY MR. ANDERSON: Q. And you've seen that patent, correct?  A. Yes, I've seen it. Q. To your knowledge, has Ethicon ever acted upon that patent and tried to produce a surgical mesh with PVDF in it for the pelvic floor or for hernia?  A. I didn't ever get any positive information for this.  Q. And then if we look at the next paragraph down, "In extremely, this patent
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?  A. Yes.  Q. And even going back to your work with Ethicon from the late '90s in the development of VYPRO?  A. Yes.  Q. And this is a letter from Christoph Walther to Quentin.  Are you familiar with a Quentin	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?  MR. THOMAS: Object to the form of the question.  THE WITNESS: Yes.  QUESTIONS BY MR. ANDERSON: Q. And you've seen that patent, correct?  A. Yes, I've seen it. Q. To your knowledge, has Ethicon ever acted upon that patent and tried to produce a surgical mesh with PVDF in it for the pelvic floor or for hernia?  A. I didn't ever get any positive information for this.  Q. And then if we look at the next paragraph down, "In extremely, this patent applications could be a strict restriction
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?  A. Yes.  Q. And even going back to your work with Ethicon from the late '90s in the development of VYPRO?  A. Yes.  Q. And this is a letter from Christoph Walther to Quentin.  Are you familiar with a Quentin Manley?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?     MR. THOMAS: Object to the form     of the question.         THE WITNESS: Yes. QUESTIONS BY MR. ANDERSON:     Q. And you've seen that patent, correct?     A. Yes, I've seen it.     Q. To your knowledge, has Ethicon ever acted upon that patent and tried to produce a surgical mesh with PVDF in it for the pelvic floor or for hernia?     A. I didn't ever get any positive information for this.     Q. And then if we look at the next paragraph down, "In extremely, this patent applications could be a strict restriction for Ethicon to sell implants manufactured
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?  A. Yes.  Q. And even going back to your work with Ethicon from the late '90s in the development of VYPRO?  A. Yes.  Q. And this is a letter from Christoph Walther to Quentin.  Are you familiar with a Quentin Manley?  A. No, I don't know.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?     MR. THOMAS: Object to the form     of the question.         THE WITNESS: Yes.  QUESTIONS BY MR. ANDERSON:     Q. And you've seen that patent, correct?     A. Yes, I've seen it.     Q. To your knowledge, has Ethicon ever acted upon that patent and tried to produce a surgical mesh with PVDF in it for the pelvic floor or for hernia?     A. I didn't ever get any positive information for this.     Q. And then if we look at the next paragraph down, "In extremely, this patent applications could be a strict restriction for Ethicon to sell implants manufactured from Pronova monofilaments. In my eyes,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. One last document. I'm going to show you Klinge Exhibit 33.  Showing you this document that we've marked as Klinge 33. Sorry.  Are you familiar with Christoph Walther?  A. Yes, I know him.  Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?  A. Yes.  Q. And even going back to your work with Ethicon from the late '90s in the development of VYPRO?  A. Yes.  Q. And this is a letter from Christoph Walther to Quentin.  Are you familiar with a Quentin Manley?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?     MR. THOMAS: Object to the form     of the question.         THE WITNESS: Yes. QUESTIONS BY MR. ANDERSON:     Q. And you've seen that patent, correct?     A. Yes, I've seen it.     Q. To your knowledge, has Ethicon ever acted upon that patent and tried to produce a surgical mesh with PVDF in it for the pelvic floor or for hernia?     A. I didn't ever get any positive information for this.     Q. And then if we look at the next paragraph down, "In extremely, this patent applications could be a strict restriction for Ethicon to sell implants manufactured

80 (Pages 654 to 657)

	Page 658		Page 660
1	flexibility, low bending stiffness,	1	Do you remember that?
2	Y-sterilization gamma without loss of	2	A. Yes.
3	tensile strength in contrast to	3	Q. He was asking you for articles
4	polypropylene, long-term stability in human		that you may have or be aware of that relate
5	body."	4 5	to what the estimated forces underneath the
6	Did I read that correctly?	6	bladder may be that the TVT® sling may be
7	A. Yes.	7	subjected to.
8	Q. And do you know that Christoph	8	Do you remember that part of
9	Walther is one of the top polymer scientists	9	your testimony?
10	at Ethicon Norderstedt?	10	A. I remember it.
11	A. Yes.	11	Q. Turning now to Klinge
12	MR. THOMAS: Object to the form	12	Exhibit 11, which was your expert report.
13	of the question.	13	A. Uh-huh.
14	QUESTIONS BY MR. ANDERSON:	14	Q. I was going to ask you some
15	Q. Did Christoph Walther ever	15	things counsel did not.
16	contact you to ask you about working with you	16	Starting with page 18 of your
17	on a PVDF mesh for Ethicon's catalog of	17	report and going through page 23 of your
18	products for either hernia repair, pelvic	18	report, in those five pages, did you go
19	organ prolapse repair or stress urinary	19	through an analysis of various literature as
20	incontinence repair?	20	well as internal Ethicon documents regarding
21	A. No, he didn't do.	21	estimated forces that one could anticipate
22	Q. Counsel asked you whether or	22	being on the TVT® sling underneath the
23	not you were aware of any clinical studies or	23	bladder neck?
24	randomized controlled trials that would look	24	MR. THOMAS: Object to the form
	Page 659		Page 661
1	at the effect of particle loss of surgical	1	of the question.
2	meshes in the tissue.	2	THE WITNESS: Yes.
3	Do you remember that part of	3	QUESTIONS BY MR. ANDERSON:
4	your testimony?	4	Q. Yes?
5	A. Yes.	5	A. Yes.
6	Q. Do you need a clinical study	6	Q. And when you gave counsel a
7	result, Dr. Klinge, in order to form your	7	measurement strike that.
8	opinion that excess polypropylene particles	8	When you listed to counsel that
9	in a human tissue can elicit a greater	9	you could anticipate less than 10 newtons per
10	inflammatory response?	10	centimeter in terms of a force that could be
11	MR. THOMAS: Object to the form	11	placed upon the sling under the bladder neck,
12	of the question.	12	is that reflected in the forces that you list
13	THE WITNESS: No, there is	13	on page 23 of your report?
14	as I tried to express earlier, there	14	A. Yes, that is a brief summary of
15	is a huge evidence that increase the	15	all this knowledge collected on these pages.
16	material, the increase of surface of	16	Q. And after you collected the
17	polymers leads to an increased and	17	knowledge that's on these pages, did you then
18	intensifying foreign body reaction and	18	use these figures on page 23 of Klinge
19	with all of the risks.	19	Exhibit 11 in order to instruct Professor
20	QUESTIONS BY MR. ANDERSON:	20	Mühl as to the forces that you thought he
21	Q. Counsel asked you some	21	should put on the machine to test the TVT®
22	questions earlier today regarding the in vivo	22	laser-cut and mechanical-cut meshes?
		23	A. In fact, that was the reason to
23 24	forces that would be realized underneath a	24	A. In fact, that was the reason to

81 (Pages 658 to 661)

	Page 662		Page 664
1	collected all of this data.	1	THE WITNESS: It is based on
2	Q. Counsel also had a statement to	2	the current data that are available,
3	you, "There are no in vivo studies regarding		which is known to Ethicon as well.
4	whether high effective porosity under stress		MR. ANDERSON: That's all of
5	will help improve biocompatibility." Taking		the questions I have for right now,
6	that statement out of your 2007 publication	5 6	Dr. Klinge.
7	with Professor Mühl, "The New Objective	7	THE WITNESS: Thank you very
8	Measurements for Porosity."	8	much.
9	Do you recall that part of your	9	MR. ANDERSON: He's got a few.
10	testimony today?	10	REDIRECT EXAMINATION
11	A. Yes.	11	QUESTIONS BY MR. THOMAS:
12	Q. Is the concept of effective	12	Q. Dr. Klinge, Exhibit 30, which
13	porosity to allow for proper tissue healing	13	was the expert report from Piet Hinoul,
14	in between the pores?	14	Mr. Anderson already showed you on page 4 of
15	MR. THOMAS: Object to the form	15	Exhibit 30 that the weight for the Prolene®
16	of the question.	16	mesh is lower than the weight that you
17	THE WITNESS: Yes.	17	typically recorded for the first generation
18	QUESTIONS BY MR. ANDERSON:	18	old Prolene®, correct?
19	Q. And is effective porosity an	19	A. I tried to calculate there
20	area that would allow for good tissue healing	20	are there has been milligram per square
21	in pore sizes that are greater than 1	21	centimeters. Usually, it's gram per square
22	millimeter in all direction?	22	meters. I assumed that the usual data of
23	A. Yes.	23	108-gram per square meter would be
24	Q. Based upon your work in this	24	10.8-milligram per square centimeters.
	Page 663		Page 665
1	area for the last 20 years, your work in the	1	Q. Do you know whether this is the
2	'90s with BIOMAT and with Ethicon, the	2	old Prolene® mesh used in TVT®
3	development of VYPRO, your publications, your	3	A. It shouldn't be the old one.
4	Congresses, all of your work in this field	4	Q. It should be the 5-mil hernia
5	for two decades, do you have an opinion to a	5	repair mesh or some other one?
6	reasonable degree of medical certainty as to	6	A. I don't know.
7	whether or not the Mühl testing in looking at	7	Q. It's this is the your
8	the 1 millimeter pore diameter of meshes will	8	best interpretation of Exhibit 30, page 4 for
9	impact the biocompatibility of that mesh in	9	the entry of Prolene® is that this is not the
10	the tissue?	10	first generation Prolene® mesh that you
11	MR. THOMAS: Object to the form	11	tested and that's used in the treatment of
12	3	12	
13	of the question.  THE WITNESS: Yes. I have no	13	stress urinary incontinence, correct?
12		14	A. I just see the name Prolene®. I see this white, and this is inconsistent to
1.4	doubte about that this is the offeet		
14 15	doubts about that this is the effect.	l .	
15	QUESTIONS BY MR. ANDERSON:	15	what we have seen with other tables where
15 16	QUESTIONS BY MR. ANDERSON: Q. And do you believe that putting	15 16	what we have seen with other tables where there was Prolene® and so this is by
15 16 17	QUESTIONS BY MR. ANDERSON: Q. And do you believe that putting the machine at a 1,000-millimeter limit is	15 16 17	what we have seen with other tables where there was Prolene® and so this is by the way, this is a report from Ethicon.
15 16 17 18	QUESTIONS BY MR. ANDERSON: Q. And do you believe that putting the machine at a 1,000-millimeter limit is based upon all of the work that you've done	15 16 17 18	what we have seen with other tables where there was Prolene® and so this is by the way, this is a report from Ethicon.  Q. I know.
15 16 17 18 19	QUESTIONS BY MR. ANDERSON: Q. And do you believe that putting the machine at a 1,000-millimeter limit is based upon all of the work that you've done for the last 20 years, you, Klosterhalfen and	15 16 17 18 19	what we have seen with other tables where there was Prolene® and so this is by the way, this is a report from Ethicon. Q. I know. A. And I would expect that they
15 16 17 18 19 20	QUESTIONS BY MR. ANDERSON: Q. And do you believe that putting the machine at a 1,000-millimeter limit is based upon all of the work that you've done for the last 20 years, you, Klosterhalfen and the rest of those involved both in Aachen as	15 16 17 18 19 20	what we have seen with other tables where there was Prolene® and so this is by the way, this is a report from Ethicon. Q. I know. A. And I would expect that they indicate clearly what they shared in their
15 16 17 18 19 20 21	QUESTIONS BY MR. ANDERSON: Q. And do you believe that putting the machine at a 1,000-millimeter limit is based upon all of the work that you've done for the last 20 years, you, Klosterhalfen and the rest of those involved both in Aachen as well as Ethicon in this area of tissue	15 16 17 18 19 20 21	what we have seen with other tables where there was Prolene® and so this is by the way, this is a report from Ethicon.  Q. I know.  A. And I would expect that they indicate clearly what they shared in their table there because this makes a lot of
15 16 17 18 19 20 21 22	QUESTIONS BY MR. ANDERSON: Q. And do you believe that putting the machine at a 1,000-millimeter limit is based upon all of the work that you've done for the last 20 years, you, Klosterhalfen and the rest of those involved both in Aachen as well as Ethicon in this area of tissue reaction to surgical meshes?	15 16 17 18 19 20 21 22	what we have seen with other tables where there was Prolene® and so this is by the way, this is a report from Ethicon. Q. I know. A. And I would expect that they indicate clearly what they shared in their table there because this makes a lot of confusion in all the subsequent when
15 16 17 18 19 20 21	QUESTIONS BY MR. ANDERSON: Q. And do you believe that putting the machine at a 1,000-millimeter limit is based upon all of the work that you've done for the last 20 years, you, Klosterhalfen and the rest of those involved both in Aachen as well as Ethicon in this area of tissue	15 16 17 18 19 20 21	what we have seen with other tables where there was Prolene® and so this is by the way, this is a report from Ethicon.  Q. I know.  A. And I would expect that they indicate clearly what they shared in their table there because this makes a lot of

82 (Pages 662 to 665)

	Page 666			Page	668
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. I just want to say it and have it  Q. And you did. A documented. Q. And you did. But so I can say it and document it, this is not the first generation Prolene® mesh, correct? A. It looks like, yes. Q. It looks like it's not? A. It looks like it's not. MR. THOMAS: Thank you. That's all I have. RECROSS EXAMINATION QUESTIONS BY MR. ANDERSON: Q. And even with a later generation Prolene® mesh, they still can't get their pore sizes or Ethicon still chooses not to get their pore sizes above 1 millimeter, correct? MR. THOMAS: Object to the form of the question. THE WITNESS: Whatever they	1 2 3 3 4 4 5 6 6 7 8 8 9 10 11 12 13 14 15 17 18 19 20 21 22 23 23 23	I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.  CARRIE A. CAMPBELL, NCRA Registered Professional Reporter Certified Realtime Reporter Missouri Certified Court Reporter #859 Illinois Certified Shorthand Reporter #084-004229 Notary Public Dated: December 3, 2013	rage	0008
24	presented there as a Prolene® there,	24			
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	yes, I agree. MR. ANDERSON: No further questions. MR. THOMAS: Thank you, Doctor. MR. ANDERSON: Thank you. (Deposition concluded at 5:16 p.m.)	1 1 2 2 3 3 4 4 5 5 6 6 7 7 1 1 2 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1	I,	Page	669

83 (Pages 666 to 669)

		Page 670	
-	 ERRATA		
2			
PAGE	LINE CHANGE/REASON		
<u> </u>			
<u> </u>		<del></del>	
, <u>——</u> -	<del></del>		
3			
0 <u> </u>			
2			
3			
4			
5 <u> </u>			
7 <u> </u>			
9 D			
J 1			
2			
3			
4			
		Page 671	
-			
2	LAWYER'S NOTES		
PAGE			
<u> </u>			
<u> </u>			
 :			
O			
1 : 2 :			
3 :			
4			
5 : 5 :			
o 7			
3			
9			
1			
O			
1			

84 (Pages 670 to 671)

Golkow Technologies, Inc. - 1.877.370.DEPS